

The MassHealth Pharmacy Program

Implementation Report

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Community Catalyst

Community Catalyst is a national non-profit consumer advocacy organization dedicated to making quality, affordable health care accessible to everyone. Founded in 1997, Community Catalyst helps advocacy organizations and grassroots groups build expertise and organizational capacity, as well as collaborate with stakeholders across health care sectors to effect positive change. Its experienced policy analysts, attorneys, community organizers and communication specialists work nationally and in more than forty states. Community Catalyst initiatives address prescription drug reform; Medicaid and SCHIP improvement and expansion; delivery system improvement; racial and ethnic health disparities; hospital accountability; insurance reform and expansion of health care access.

Community Catalyst is a leading consumer voice on a wide range of prescription drug issues. Its Prescription Access Litigation (PAL) campaign supports class action law suits that challenge illegal industry practices, which have resulted in \$1 billion in awards to consumers and health plans over the last eight years. Partnering with the Alosa Foundation, sponsor of the Independent Drug Information Service, PAL received settlement funds in two cases to create *Generics Are Powerful Medicine*, an innovative consumer education initiative. In 2006 Community Catalyst, with the support of The Pew Charitable Trusts, developed The Prescription Project, which was launched in 2007 with a focus on addressing conflicts of interest created by pharmaceutical marketing and on promoting an increased physician reliance on independent evidence of drug effectiveness. www.communitycatalyst.org

Pew Prescription Project

This study was funded by The Pew Charitable Trusts, as part of the work of The Prescription Project. The Project has been successful in leading policy change at the state and national level and among academic medical centers and other private institutions. Building on these accomplishments, the Trusts created the Pew Prescription Project in 2009 to conduct rigorous research and promote consumer safety through reforms in the approval, manufacture and marketing of prescription drugs, as well as through initiatives to encourage evidence-based prescribing. www.prescriptionproject.org

Foreword

In 2001, the Massachusetts Medicaid program—MassHealth—took the first of a series of steps to respond to rapidly escalating drug costs, including the phased introduction of the MassHealth Drug List (MHDL), among other initiatives. Often called a “preferred drug list” in other states, the MHDL designates which drugs are recommended as first line treatment and which require prior authorization before prescriptions can be filled. The Prescription Project at Community Catalyst commissioned this report, in conjunction with the Massachusetts Medicaid Policy Institute, to better understand the strengths and weaknesses of this process. This evaluation shows that consumers and other stakeholders view the Massachusetts Medicaid Pharmacy Program as a process that, in its implementation to date, has made considerable efforts to balance cost and quality considerations.

Massachusetts is one of 44 state Medicaid programs that have introduced preferred drug lists, along with other strategies to address increasing prescription costs. Public and private payers throughout the country have been grappling with escalating pharmaceutical costs for many years. In 2001, these costs represented 13.6 percent of total healthcare spending in the U.S., and 12 percent in Massachusetts. Because general health care inflation consistently outstrips economic growth and tax revenues, state Medicaid costs have become a growing percentage of budgets in most states. Faced with the necessity of balancing their budgets and the pressure of an increasing number of uninsured residents, states have been forced for many years to address the cost containment challenges that now confront the Obama administration and Congress as they look to design a sustainable plan for national health care reform.

Attempts to curb growth in pharmaceutical expenditures risk harming patients when they deprive them of clinically appropriate treatment. Yet patients can also be put at risk due to prescribing of inappropriate drugs or too many drugs. Industry marketing frequently emphasizes new and expensive agents over established therapies that are less expensive and equally effective. To ensure quality, sustainable, patient-centered care, therapeutic decisions should instead be based on the best available evidence, unbiased clinical evaluation by prescribers, and good communication between clinician and patient. The importance of these principles is reflected in current national efforts to improve quality by expanding resources for research to compare treatments and to fill evidence gaps, such as the lack of studies that include racial and ethnic minorities, seniors and women.

The Massachusetts Medicaid Pharmacy Program addressed these challenges by putting clinical considerations first when designing pharmaceutical cost containment methods, and by a careful implementation process. In their approach:

- The program adopted a well-designed decision-making structure and criteria for evidence review panels to ensure that clinical considerations balanced financial ones.
- The Program avoided restrictions based on negotiated pricing or arbitrary coverage limits.
- A local medical school led the synthesis of clinical evidence.
- The implementation process was gradual and inclusive of consumer and patient advocacy groups, who were also invited to review the clinical evidence so long as their representatives had clinical expertise.
- The concerns of mental health advocates were addressed by setting aside the most contentious clinical issues when implementing the drug list. Mental health drugs are included in several targeted drug management initiatives.
- Pharmaceutical companies were excluded from the clinical review process.

The MassHealth Pharmacy Program achieved significant cost savings, according to data supplied by the Program. Savings were reported to be \$99 million in the first year. The annual growth rate in MassHealth drug spending was significantly reduced, and growth trends have been lower than national trends since. The Program's internal monitoring processes and an engaged advocacy community appear not to have found significant adverse clinical results, but independent research is still needed to confirm this.

With the passage of comprehensive health reform in Massachusetts in 2006 and the enrollment of 72,000 more residents in the Program, quality and cost initiatives such as the MassHealth Pharmacy Program have become even more critical to sustaining access to care.

The MassHealth Pharmacy Program's positive results also stand in contrast to problems created when patients that were dually eligible for Medicaid and Medicare were transferred to Medicare D private pharmacy plans in 2006. Administrative costs were significantly higher, and Medicare D paid 30 percent more on average for drugs than Medicaid, which produced a windfall of over \$3.7 billion nationally for drug manufacturers from 2006-2008.¹ Furthermore, patients were moved from the comprehensive drug coverage of Medicaid into restrictive, complex private drug plans that significantly disrupted access to necessary drugs.²

It is our hope that the lessons from an evaluation of the Massachusetts experience will help to inform similar efforts in other public programs. The MassHealth Pharmacy program and other well-designed Medicaid drug programs can be an important model for state and national efforts to expand comprehensive access while managing resources well, protecting patients, and using an evidence-based approach to clinical decisions and program design. The MassHealth experience also demonstrates that programs can successfully involve consumers, providers, researchers and policymakers in the ongoing process of appropriately incorporating new drugs and technologies into treatment.

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¹United States House of Representatives Committee on Oversight and Government Reform. Majority Staff. *Medicare Part D: Drug Pricing and Manufacturer Windfalls*. July, 2008.
²Shumway, M. and Change, S. *Impact of Medicare D on Access to Antipsychotic Drugs and Hospital Costs among Dual Eligibles in California*. California Program on Access to Care, Findings. March, 2008.

Executive Summary

MassHealth, the Massachusetts state Medicaid program, serves 1.19 million low-income state residents, with an annual budget of 8.2 billion.³ The MassHealth Pharmacy program is responsible for providing and managing prescription and selected over-the-counter (OTC) medications for all non-Medicare beneficiaries, with the exception of those in managed care. In addition, MassHealth fills in coverage gaps for uncovered drug classes for the 220,000 dual eligible beneficiaries who were transferred to private prescription drug coverage in 2006 as a result of the Medicare Modernization Act of 2003. The MassHealth Pharmacy program has as its foundation several components: the MassHealth Drug List (MHDL), which designates which drugs require prior authorization for dispensing; drug management strategies stressing appropriate drug use and generics when indicated; drug price management; monitoring of quality; provider, pharmacist, and patient education; and the setting of benefit design and other policies. In state fiscal year (FY) 2009, MassHealth Pharmacy services are expected to account for approximately 6.2 percent of the MassHealth budget.

In November 2001, in response to the rapidly escalating pharmacy costs, an increase common to all state Medicaid programs at the time, the state revised program regulation 130 CMR 406.4, requiring prescribers of MassHealth patients to obtain prior authorization for brand drugs that had exact generic equivalents. In association with this regulation, MassHealth created and implemented the MassHealth drug list (MHDL). The MHDL designates covered drugs, under what conditions those drugs are covered with prior authorization, and summarizes relevant clinical evidence for prescribers. Unlike most states with a preferred drug list, Massachusetts has not regularly used supplemental rebates from pharmaceutical companies as a factor in determining preferred drugs. Since implementing this program and incorporating the MHDL with other drug management components, MassHealth has slowed the increase of pharmacy costs on a number of parameters. It has decreased the proportion of Medicaid dollars spent on pharmacy and has increased the proportion of prescriptions that are generic. The growth in price for brand prescriptions has escalated unabated. As a result, MassHealth spending compares favorably in relation to overall national drug spending trends, and to the trends in state Medicaid pharmacy spending growth since 2001. Furthermore, the timing of the MHDL implementation positioned the state to maximize savings from implementation of the Medicare Drug Benefit in 2006 and forward. In spite of demonstrated savings, no systematic evidence suggests that cost savings have been achieved by forfeiting appropriate clinical care.

This report documents the process of implementation of the MassHealth Pharmacy program, including the development and implementation of the drug list and activities surrounding its management. In particular, the primary focus of this report is the implementation of the MHDL, and, to the extent possible, its impact on beneficiaries. This report does not address the role of stakeholders in development of the pharmacy program prior to development of the drug list, nor does it quantitatively analyze the impact of the drug list on health outcomes of the MassHealth covered population.

We approached this work as a modified program evaluation/implementation study. We limited our focus in a number of ways to allow us to provide a useful picture of the program within the time constraints imposed. We begin our analysis with the program's inauguration



³FY 2008 figures provided by MassHealth. Enrollment includes 403,000 individuals contracted out to managed care organizations, 315,000 in Primary Care Clinician Plan (PCCP) Medicaid managed care, and 471,000 who are in fee-for-service (among them approximately 220,000 dual eligible beneficiaries).

of its clinical work groups and we have focused on the program's structure, decision-making processes and overall implementation. Political activities prior to this period were not studied. Additionally, we have examined program outcomes solely by using existing data. Financial outcomes were discussed based on official state reports and presentations. Clinical outcomes could not be directly studied, but several sources of information were gathered to assess indications of clinical impacts of the program, rather than to analyze them definitively.

Finally, we approached this project as a stakeholder analysis. Over 30 individuals were interviewed for this report including current and former MassHealth Pharmacy officials and staff. Particular efforts were made to include outside stakeholders who represented providers, consumer advocates, and physicians. We did this with the understanding that a major change in a program touching hundreds of thousands of vulnerable citizens is more than simply a technical exercise but is a politically important action. Its legitimacy, and indeed its long-term success, depends on a broad consensus regarding both its process and its impacts. Documentary evidence was also gathered from the program itself in the form of memos, internal and public reports, and limited raw data. Memos and reports from a variety of stakeholders were also gathered.

Key findings of this report include:

- The Massachusetts model is a successful approach to pharmaceutical cost containment that relies overwhelmingly on a clinical approach, avoiding the pitfalls or restrictions based on negotiated pricing or arbitrary coverage limits.
- The strong integrated presence of a medical school at the core of the MassHealth Pharmacy program has provided ongoing clinical expertise and a sustained focus on quality of care in policy considerations.
- As a result of implementation of the MHDL, as well as other drug management tools, educational support and other cost containment services since 2001, financial successes include the following:
 - Savings were estimated by MassHealth to be at least \$99 million in the first year of the program.
 - The annual rate of growth in MassHealth prescription drug spending decreased from 13 percent in 2001 to 5 percent by 2003, and minus 1 percent in 2008 (Figure 4).
 - Generic use rate is currently 80 percent of prescriptions, among the highest reported in a health system.
 - According to national data, MassHealth drug spending per enrollee averaged \$26 less than the national average in 2004 (\$797 versus \$823, Figure 6), and growth trends are lower than national trends for Medicaid pharmacy programs, at 0.6 percent versus the national average of 7.4 percent in 2004 (Figure 8). This was accomplished in a generally high-cost state, without draconian measures taken by some other states such as limits on the number of prescriptions covered.
- In contrast to some other states' experience, the inclusive development and staged implementation of the MassHealth drug list has been accepted by most providers with considerable success and limited resistance by advocates. However, advocates are maintaining active interest in the program's ongoing drug management, and are prepared to challenge any increased restrictions on medications, particularly in the area of mental health.

- According to several qualitative and quantitative metrics, the MassHealth Pharmacy program appears to be managing costs and internally monitoring quality without significant evidence of adverse clinical results. However, no transparent and systematic research by outside entities has been undertaken to the degree necessary to confirm this. Such unbiased research is the only way to adequately evaluate the true clinical impact of MassHealth drug cost management.
- The program's commitment to the primacy of clinical criteria was designed to protect patients and give it credibility among stakeholders.
- The review process for most drugs being considered for restriction was open to outside experts, providers, and patient advocacy groups. This ensured input from stakeholders strongly focused on patient protection and allowed buy-in from groups that might otherwise have made the implementation more difficult.
- Timely responses to the concerns of advocates, especially in the area of mental health, allowed the most contentious issues to be set aside so that implementation of the remainder of the program could proceed expeditiously.

Background: Major features of MassHealth

Overview of MassHealth

MassHealth currently serves 1.19 million members, reflecting annual growth in enrollment of four to five percent in recent years.⁴ Enrollment includes 403,000 individuals contracted out to managed care organizations, 315,000 in the Primary Care Clinician Plan (PCCP) Medicaid managed care, and 471,000 who are in fee-for-service coverage. Fee-for-service membership also includes approximately 220,000 members who are dually eligible for both Medicare and Medicaid (dual eligible beneficiaries). The MassHealth Pharmacy program is responsible for providing and managing prescription and selected over-the-counter (OTC) medications for all beneficiaries in fee-for-service or PCCP programs. In 2006, with implementation of the Medicare Modernization Act of 2003, primary prescription drug coverage for dual eligible beneficiaries was transferred to private Medicare drug plans. However, MassHealth covers those drug classes that are not covered through Medicare, which includes certain mental health and all OTC medications.

As of state fiscal year 2008, MassHealth's budget of \$8.26 billion accounts for two-thirds of the state Executive Office of Health and Human Services budget (\$13.5 billion), and nearly one-third of the Massachusetts state budget of \$28.2 billion. According to program officials, in FY 2008, the MassHealth pharmacy program budget (including the Federal portion, or matching funds) was \$493 million, or 5.97 percent of the MassHealth budget. In 2007, the most recent year that comparable national figures are available, MassHealth pharmacy costs accounted for 6.3 percent of the state Medicaid non-managed care acute care spending, compared to a national average of 11.1 percent (Figure 1).⁵ It should be noted that a higher proportion of Massachusetts beneficiaries are in managed care than are in managed care



⁴2008 figures provided by MassHealth.

⁵Kaiser Family Foundation, State Health Facts website (www.statehealthfacts.org), accessed October 15, 2009. When Medicaid payments to managed care and health plans are included, pharmacy spending is 4.6 percent of state Medicaid acute care spending, compared to the national average of 7.7 percent.

nationally. Therefore, MassHealth Pharmacy is directly responsible for pharmacy costs for a smaller proportion of beneficiaries than are many other state Medicaid programs. Figure 2 indicates the distribution of MassHealth members by eligibility status. Comparison is limited due to the different proportions of members in managed care in Massachusetts compared to national data. However, overall, MassHealth includes more disabled and elderly than the national average. These are groups that use prescription drugs to a high degree, and to the extent comparisons are possible, higher prescription drug use and spending might be expected.

Program structure

The MassHealth Pharmacy Program is comprised of three main operational entities, including a private sector claims administrator, a policy division, and a clinical component (Figure 3). The strong integrated presence of a medical school in drug management is unusual among Medicaid programs. Together these three entities provide development and ongoing operations. Because this structure is one of the strengths of the program, the role of each is described below:

MassHealth Pharmacy policy division: This division of the program provides all policy leadership for the program. This includes development and monitoring of all clinical, pricing and reimbursement policies, and financial direction. The policy division generates policy analyses, clinical reports, and maintains ultimate decision authority for all policies. The policy division also includes the MassHealth Drug Utilization Review Board. This advisory group is comprised of eight physicians and eight pharmacists, and serves as the consultative component of the program. Members of the Board are appointed by the MassHealth Pharmacy director, and all formally assert they have no conflicts of interest. The group meets quarterly, with meeting minutes posted on the MassHealth website. Topics of discussion have included: newly-approved drugs and their placement on the drug list, changes in the drug list and management strategies, retrospective drug use review, quality review, review of financial status, and new program initiatives.

University of Massachusetts Medical School (UMMS): This is the clinical component of the program managed by the Clinical Pharmacy Services unit at Commonwealth Medicine. It includes physicians, pharmacists and pharmacy assistants engaged in clinical reviews and prior authorization activities. Tasks undertaken for MassHealth Pharmacy at the medical school include new product reviews, therapeutic class reviews, and maintenance of the MassHealth Drug List. UMMS also conducts the federally-mandated drug utilization review (DUR) and prior authorization process on behalf of MassHealth. In addition, UMMS is responsible for quality review of the MHDL and the prior authorization program. Physicians on staff are also required to sign conflict-of-interest statements.

ACS State Health Care: ACS State Health Care is a private management company that provides pharmacy benefit management, administrative support and a range of other management services to nearly half of all states. As the claims processor for MassHealth Pharmacy, ACS conducts all support for payment and financial management, and maintains eligibility and clinical data for members. ACS provides software for point of service claims adjudication through the MassHealth Pharmacy Online Processing System (POPS), and software to support prior authorization. ACS' "Smart PA" software uses algorithms created for use with MassHealth data systems to link patients to drug coverage decisions at the point of service. This process allows pharmacists to bypass, when possible, the need for physicians to submit prior approval requests on paper. For example, if a particular diagnosis is required for a restricted medication to be approved, the system will access this

information automatically when the claim is submitted at the point of service to ascertain immediate approval, rather than requesting information from the physician. Thus the physician does not have to submit paperwork to support approval of the medication for that particular case.

The MassHealth structure serves as a major strength of the program in several ways. The policy group draws clinical expertise and credibility from an established clinical entity based at a medical school. This not only provides exceptional access to expertise but confers credibility on the group's recommendations. In addition, ACS state health care provides claims processing and other administrative support. Specifically, ACS provides the software that allows for bypassing the prior authorization process in cases where the Medicaid data system (MMIS) data already contains the necessary current diagnoses and other up-to-date patient information.

Drug management

Several features serve as the foundation of the MassHealth Pharmacy program. These components of the program have been implemented with the goal of cost containment in the context of appropriate clinical decisions. Major components that have been implemented and are ongoing since 2001 include:

- The MassHealth Drug List (MHDL): a list of medications that are covered by MassHealth, with coverage rules and restrictions, which is continually updated.
- Drug price management that includes a maximum allowable cost (MAC) system, which sets the maximum reimbursement allowed for each prescription. While all states have a MAC system, Massachusetts is unusual in that reimbursements for drugs are set at a "usual and customary" price, defined as the lowest price charged or accepted by the retail pharmacies. For example, if a retail chain offers a generic drug for \$4, that is the maximum price MassHealth will pay for that medication.
- Generics First, a program in which generic drugs are incorporated into step therapy as the first choice drug.
- Additional cost containment/management strategies include limits on quantity of pills per prescription, and limited access to early refills.
- "Smart PA": a claims management system in which prior authorization is facilitated by use of claims history to determine at point of service whether medications are approved, thereby bypassing manual prior authorization requests.
- Ongoing monitoring of quality of care for impact of drug restrictions on overall medical utilization and costs.

The MassHealth Drug List (MHDL)

According to MassHealth officials, the purpose of the MassHealth drug list is: to indicate prior authorization status for all covered medications; to provide comparisons between drugs within a given class; and to provide selected clinical information and links to clinical evidence for prescribers to consider in management of patients. Recently, the posted MHDL Therapeutic Class Tables have added prior authorization evaluation criteria. The MHDL is based on clinical evidence, and was developed with input from the University of Massachusetts Medical School's clinical reviews, the Drug Utilization Review Board, and several diagnosis-specific clinical consultant groups that have been convened to address drug coverage for various therapeutic areas.

Initial implementation of the MHDL was staged by drug class (see Table 1). As of 2008, 37 classes had established guidelines and are available publicly (www.Mass.gov/druglist); classes are being added on an ongoing basis. Between August 2002 and June 2003, the MHDL was enacted, and therapeutic classes which would require prior authorization were “rolled out” to the drug list in a staged approach: The first several therapeutic classes were selected based on the prevailing consensus they would pose the least health risk if placed under restriction: gastrointestinal agents (proton pump inhibitors and histamine-2 antagonists), non-steroidal anti-inflammatory drugs, antihistamines, and statins.

The process for adding drugs to the list or changing restrictions on current medications is similar to that which takes place in other states and in private programs:

- Initial review – DUR Staff
- Primary literature
- Product literature
- Comparative analysis (clinical & financial)
 - Senior DUR staff review
 - Clinicians consulted (clinical workgroups convened by Medicaid and outside experts)
 - Recommendation made to MassHealth Pharmacy Policy Committee

Based on interviews with current and former MassHealth staff, and outside stakeholders, development of the drug list is driven by clinical evidence. Clinical concerns are the entire focus of the clinical workgroups and consultants. A vigorous outreach effort has ensured clinical representation from many affected groups. This focus and process will be discussed later in detail as an implementation issue.

Unlike most state Medicaid program drug lists, the MHDL makes use of supplemental rebates for only a few drugs. Supplemental rebates are additional savings beyond the standard legislated Medicaid rebate provided by manufacturers to the program based on sales of particular drugs. Supplemental rebates are negotiated directly between states and pharmaceutical manufacturers, providing additional discounts, in the form of rebates, for drug costs to the state for designating their drugs as preferred (not subject to prior authorization). While almost all states see this as an important income stream, at the outset of the development of the drug list, MassHealth officials made an explicit decision to avoid this approach. The reasons provided by MassHealth officials are several, including doubts regarding the true long-term savings of this policy. The primary reason stated by both current and former officials was a perception that placing drugs on the MHDL based on price discounts would undermine the clinical credibility of the drug list.

Managing the Drug List

The MHDL is managed primarily through the prior authorization (PA) process. The dual goals of this process are to ensure that all medications dispensed to MassHealth members are clinically indicated while costs are minimized. The overall PA process is managed by UMMS. It is worth noting that, as an effort to minimize disruptions caused by policy changes, patients are “grandfathered” in if a medication becomes restricted. “Grandfathering” lasts for the life of the prescription, or for however many refills remain. While there is some concern about whether this is adequate protection for patients, physicians can submit PA requests to extend the medication when clinically warranted.

Criteria for prior authorization in MassHealth follow a standard pattern and restrictions include:

- Generic equivalence – same drug
- Therapeutic equivalence – different drug, unless the prescriber can demonstrate the medical necessity of the non-preferred drug
- Step therapy – use of the lower cost alternative first
- Quantity Limits – provide a supply for a limited period of time, or a limited dose
- Narrow patient selection criteria – typically high-cost new-to-market biotechnology, or for specific safety concerns
- Dosage form – e.g., combination or sustained release drugs
- Off-label use – some drugs are frequently used for indications not approved by the FDA and not well-supported by clinical evidence

Prior authorization

Prior authorization activities leading to approvals or denials of prescriptions take place primarily at the University of Massachusetts Medical School. In addition to physician advisors, prior authorization and other utilization review activities are done by eight to nine full-time pharmacists, seven to eight per diem pharmacists, and eight assistants. Prior authorization is paper-based, with no telephone approvals, and forms must be submitted by physicians by fax or mail. It is not unusual for Medicaid programs to rely solely on faxed prior authorization requests. The Program provides over 20 different downloadable forms based on therapeutic drug class. MassHealth officials see this as a way of making the forms more focused and easier to fill out. Yet some physicians interviewed experience it as confusing and cumbersome. For each medication that requires prior authorization, an individual form must be completed and faxed, which requires basic patient information to be filled in each time. This sometimes results in multiple forms for the same patient within the same visit.

MassHealth officials report that the utilization management program averages about 300 calls per day from providers that are associated in some way with prior authorization requests. Calls involve requests regarding why particular medications were denied, or further clarification on requests. On average, about 7000 requests per month are submitted through the system. (See Appendix 1 for a flow chart illustrating the prior authorization process). MassHealth reports that prior authorization requests are involved in less than one percent of the 900,000 monthly pharmacy claims, although this statistic alone is of little value without understanding the details of which drugs are subject to prior approval, which requests are approved, and which requests are denied. When a prior authorization decision is made (approval or denial), an automated response is sent to three parties: the

requesting physician, the pharmacy, and the patient. According to a MassHealth 2005 report, 99 percent of all responses were generated within 24 hours, although these include responses merely asking for additional data.

The denial rate for prior authorization is now estimated by MassHealth at about 40 percent of all 7,000 faxed requests per month. Prior authorization requests cover a wide range of content, from requesting a particular medication and bypassing step therapy, to requesting medications limited to certain diagnoses, or particular preparations of a common drug. The most common medication classes among prior authorization requests are: anticonvulsants; antidepressants; antipsychotics; narcotics; hypnotics; respiratory; and gastrointestinal drugs (see appendix for details regarding current management of some of these classes). While we report this denial rate to provide some information about activities and process, we again note that prior authorization denials rate is of limited usefulness. Common reasons for denials include insufficient information and lack of evidence of step therapy.⁶ That is, they are often not substantive refusals but requests for more information. In addition, the monthly denial rate does not indicate how many denials are approved ultimately, nor the extent to which a delay in approval actually occurs. For these reasons, interpretation of requests and denials on a monthly basis is difficult, and was not provided at this time.

An appeals process is also in place for denied requests. This must be initiated by the patient within 30 days of written notification of the denial, which is sent to patients by MassHealth. According to MassHealth officials, 61 appeals went to a hearing in FY 2006. Officials estimate that about 99 percent of appeals are resolved at the hearing by the arbitrator in favor of MassHealth, or are dismissed due to a settlement prior to the appeal. The member may continue to receive the medication pending the outcome of the appeal only if the member had been on the medication previously, and if the appeal request was made within 10 days of the denial notice being mailed out.

The MassHealth Drug List – Clinical and comparative considerations

An in-depth analysis of the clinical appropriateness of the MassHealth drug list and impact of prior authorization process is beyond the scope of this report. However, as over 40 states have implemented a preferred drug list, and most have established or plan to establish controls on mental health drugs,⁷ several professional organizations have created or summarized the characteristics of an optimal drug list and prior authorization process for application to Medicaid programs.^{8,9} Such process and structural characteristics include, among other features: Consultation with experts and a range of Medicaid providers regarding drugs that are restricted; wide publication of restricted drugs and associated exemptions; exemption from prior authorization for many psychiatric, antiviral and anti-convulsive medications (because of the lack of clinical consensus on the interchangeability

⁶Note that early refills are not subject to the prior authorization process. If a request for an early refill is made, it is done by the pharmacist at the behest of the member. As such, it is not a prior authorization request, it is termed a “clinical certification” request. This distinction is important because certification requests cannot be appealed, as can prior authorization requests.

⁷Kaiser Family Foundation, www.Statehealthfacts.org

⁸Kaiser Commission on Medicaid and the Uninsured: *A Model Prescription Drug Prior Authorization Process for State Medicaid Programs*, April 2003, prepared by the National Health Law Program.

⁹Owens MK. National Pharmaceutical Council. *State Medicaid Program Issues: Preferred Drug Lists*, January 2003. (Available at: [http://www.npcnow.org/research/medicaid pharmaceutical plan resources](http://www.npcnow.org/research/medicaid%20pharmaceutical%20plan%20resources)).

of these drugs and the risk of clinical and social complications in these populations); brand drugs with narrow therapeutic indices; drugs in which side effects have been identified in the generic equivalent; and drugs related to organ transplants. In terms of process, the model system is expected to have: prior authorization response within 24 hours; 72-hour emergency supply available at the point of service while authorization is being obtained;¹⁰ retrospective review of denials; patient surveys to address consumer access. In general, the MassHealth drug list and management of the list through prior authorization complies with these requirements.

In addition, a side-by-side comparison of the MassHealth drug list in 2007, both with other insurers within Massachusetts and with other state Medicaid programs revealed that MassHealth's covered drugs did not differ widely from other insurers in Massachusetts at the time. According to a list published by the Massachusetts Medical Society comparing formularies and coverage for major insurers within the state,¹¹ MassHealth does not generally restrict medications that other insurers do not. A count of restricted drugs on the MHDL also conducted for this report in 2007 found that of the top 100 most commonly-used brand drugs, 45 have some prior authorization or coverage restriction, including four uncovered drugs (for erectile dysfunction) and nine with prior authorization limited to age or dosage form. When these are excluded, 32 medications of the top 100 are under prior authorization due to other reasons. These numbers are comparable to that reported by other Medicaid programs, although the specific drugs included are likely to differ due to different time frame and details of analysis.¹² However, such formal comparisons are limited, as the details of the prior authorization approval process better determine the degree to which access is truly restricted.

In an effort to better place drug management into the context of other states' management of drugs, the MassHealth prior authorization process was also compared to that of other states. Drawing from a series of studies by Fischer et al., in which Medicaid programs were surveyed in 2005 to determine details of the prior authorization process,^{13, 14, 15} it was observed that MassHealth was more restrictive than most other states in the following classes:

- Coxibs (arthritis/pain medications such as Vioxx and Celebrex): MassHealth was one of the relatively small number of state Medicaid programs that used all five of the clinical criteria supported by evidence from the medical literature as part of prior authorization.
- Angiotensin receptor blocker drugs (ARBs, a cardiovascular drug class): One of the 3-4 most stringently evidence-based states, MassHealth required use of an ACE-inhibitor before approving an ARB.
- Antidepressants: These requirements were reasonably stringent, with several of the higher-cost antidepressants restricted to a "fail-first" approach, requiring that other preferred medications be tried prior to approval of a non-preferred drug.

¹⁰In this case, emergency is defined as, "serious, health threatening medical situations when any delay in access to the medication could cause the recipient to suffer serious or permanent harm to his or her health, or result in hospitalization or emergency room treatment, or the recipient has a serious contagious disease which, if left untreated, could pose a significant public health threat," (KCMU, A Model Prescription Drug Prior Authorization Process for State Medicaid Programs, 2003). The way in which a Medicaid program interprets this definition is a critical factor.

¹¹Massachusetts Medical Society, Massachusetts Outpatient Formulary Guide, 10th Edition, 2007.

¹²Kaiser Commission on Medicaid and the Uninsured, Case study: Michigan's Medicaid Prescription Drug Benefit, January 2003.

¹³Fischer MA, Schneeweiss S, Avorn J, Solomon DH. Medicaid Prior-Authorization Programs and the Use of Cyclooxygenase-2 Inhibitors. *N Engl J Med* 2004;351:2187-94.

¹⁴Fischer MA. Restrictions on Antidepressant Medications for children: A review of Medicaid policy. *Psychiatric Services* 2007; 58(1):135-138.

¹⁵ MA, Choudhry NK, Winkelmayer WC. Impact Of Medicaid Prior Authorization On Angiotensin-Receptor Blockers: Can Policy Promote Rational Prescribing? *Health Affairs* 2007;26(3):800-807.

- Biologic medications for rheumatoid arthritis: MassHealth requires prior authorization for most of these medications, placing it among more restrictive states based on amount of information and documentation required.

Most state Medicaid pharmacy programs report targeted initiatives for particular areas of drug management. A review of several of the specific clinical programs MassHealth implements to manage drugs was also conducted by one of the authors (MF) for this report. In terms of several specific cost containment/clinical appropriateness programs, a clinical expert analysis of several selected cost management programs was conducted. Findings are detailed in Appendix 2, and include antipsychotics, anticonvulsants, respiratory and pain medications. From available information, these programs appear to reflect appropriate clinical practice.

MassHealth has demonstrated some degree of flexibility in terms of reversing decisions when analysis indicates that restrictions are too strong. A recent example provided by MassHealth is the placement of restrictions on methylphenidate skin patch (Daytrana®), a newly-approved preparation to treat attention deficit hyperactivity disorder (ADHD) that contains the same ingredients as available oral methylphenidate. Prior authorization required that patients receiving Daytrana® be between 6-12 years of age have medical necessity for transdermal formulation (i.e. swallowing difficulties) AND a history of claims of contraindication to long or intermediate acting methylphenidate. After implementation of this policy in 2006, all requests and denials were reviewed by MassHealth clinical experts for the four months following implementation. In this review, an 80 percent denial rate was found, and reasons were reviewed in detail. It was recommended that the restrictions be relaxed, to include either medical necessity (documented) OR inadequate response or adverse reaction to long or intermediate acting oral methylphenidate or therapeutically similar product. Although considerable restrictions remain, the program demonstrated detailed clinical review and responsiveness in this particular case. Another recent example provided by MassHealth officials, is the medication Byetta® (exenatide), an injectable brand drug for diabetes. In this case, during the first six months on prior authorization in 2008, comments were received that the rules were too stringent, and MassHealth identified a denial rate of 87 percent. After further review of updated evidence-based guidelines for use, MassHealth relaxed the requirement for step-therapy prior to use of Byetta®.

The MassHealth Pharmacy program reports that it regularly monitors clinical indicators to determine any unintended adverse clinical or other consequences resulting from added restrictions to covered drugs. As one of several examples of this drug class review provided for this evaluation, a 2005 impact analyses of the placement of prior authorization restrictions on proton pump inhibitor (PPI) medications, coxibs, and hypnotics was provided. In each of these analyses, these monthly statistics were reviewed and reported for the year following implementation: drug utilization and spending; prior authorization requests and denials; hospitalizations and other services used by those denied approval of restricted drugs (and associated costs for shifting); and a review of medication-specific adverse events (i.e., gastro-intestinal-related diagnosis for patients denied coxibs). However, we were not provided with a schedule for how often such reviews are revisited, or with raw data with which to conduct such a review.

Similarly, to date, no outside analysis has been conducted to determine the clinical impact of the drug list, prior authorization, and other MassHealth drug management programs. There is no doubt that drug management services such as limiting polypharmacy and

utilization review that results in more appropriate use of medications results in improved clinical care. However, some general literature suggests that prior authorization and other medication restrictions are associated with several clinical impacts on Medicaid beneficiaries in terms of gaps in adherence, hospitalizations, emergency department visits.^{16, 17, 18} Several state programs have been criticized for the absence of systematic outside evaluation on the grounds that public programs require transparency to establish confidence in clinical appropriateness of drug management processes.

Cost Impact of MassHealth Drug List and Pharmacy Management

Initial implementation savings

By financial measures, the MassHealth Pharmacy program and implementation of the drug list has resulted in considerable cost savings to the program, without imposing some of the more draconian measures taken by some states, such as monthly limits on the number of medications dispensed. MassHealth reports that implementation of the drug list in the first year of the program resulted in \$99 million in cost avoidance specific to drug programs (methodological details of cost models were provided by MassHealth). Savings reported by MassHealth include those realized through use of quantity limits, dosage limits, age limits, and therapeutic substitution. Selected components and some additional savings include the following:

- Brand prior authorization – \$43 million cost avoidance first full year of implementation
- Early refill edit – \$29 million cost avoidance first full year of implementation
- Weekly update of maximum generic pricing formula, 130 percent of lowest published generic price – \$12 million cost avoidance first full year of implementation

As indicated in Figure 4, the MassHealth Pharmacy program appears to have changed the trend in program spending by 2004 and spending growth decreased through 2008, though data are not comparable after 2005 due to the implementation of Medicare Part D.¹⁹ During this time period (2001-2008), other factors also contributed to pharmacy spending trends, so savings can not be attributed solely to MassHealth Pharmacy initiatives. Those factors include increased managed care as a proportion of total enrollment (which decreased pharmacy program spending) and increased overall MassHealth enrollment (which increased pharmacy program spending).²⁰ Nevertheless, the decrease in spending after 2002 suggests that considerable savings were realized through initial drug management approaches. This was accomplished as MassHealth initially targeted

¹⁶Soumerai SB. Benefits and Risks of Increasing Restrictions on Access to Costly Drugs in Medicaid. *Health Affairs* 2004; 23(1):135-146.

¹⁷Muraski MM and Abdelgawad MA. Exploration of the impact of preferred drug lists on hospital and physician visits and the costs to Medicaid. *American Journal of Managed Care* 2005;11:SP35-SP42.

¹⁸Soumerai SB Zhang F, Ross-Degnan D, et al. Use of Atypical Antipsychotic Drugs for Schizophrenia in Maine Medicaid Following a Policy Change. *Health Affairs*, May/June 2008; 27(3): w185-w195.

¹⁹Note that beginning in 2006, the implementation of Medicare Part D substantially decreased coverage responsibility for dual eligible enrollees.

²⁰Between 2001 and 2008, the proportion of MassHealth members in managed care, for which MassHealth pharmacy is not responsible, increased from 18 percent to over 30 percent, so that MassHealth pharmacy was responsible for a smaller proportion of beneficiaries each year, contributing to decreased spending. During this time period as well, overall enrollment in MassHealth also increased by approximately 20 percent, and MassHealth retains a disproportionate share of the disabled population compared to the managed care plans.

polypharmacy, unit costs, and management of therapeutic classes that were expected to have the greatest opportunity for savings while posing limited risk to patients. On the other hand, the high cost of brand drugs continues to exert pressure on drug cost management (see below).

Pricing impact: A major target of cost savings has been addressing the price per prescription, in terms of both lower cost-per-brand prescription, and increasing the proportion of prescriptions dispensed that are low-cost generic drugs. As shown in figure 5, the average price of brand-name drugs increased sharply over this time. At the same time, the fact that the average cost-per-claim overall (including both brand and generic drugs) has leveled off indicates that MassHealth has been able to increase the use of generic drugs, largely offsetting brand drug price trends.

According to program statistics as of mid-2008, generic drugs comprise 78 percent of MassHealth prescriptions dispensed. This is among the highest reported rates among both Medicaid programs and private health plans. The mix of generic and brand drugs resulted in a decrease in the overall price per prescription. As well, the average cost-per-claim for both generic and brand drugs stabilized or slightly decreased in the most recent year reported (2007).

Figures 6 through 8 place MassHealth Pharmacy costs and savings in the context of national data and other state Medicaid programs along several metrics. The National Health Expenditure estimates on which these were based are calculated by the federal government for all states and the nation, and include both fee-for-service and managed care spending estimates allocated by service. Figure 6 indicates that after 2002, annual Medicaid (MassHealth) spending per enrollee for drugs and other durables in Massachusetts remained relatively flat compared with national averages of about 10 percent annually. Similarly favorable patterns were seen in Massachusetts compared to national spending on prescription drugs as a percent of total Medicaid personal health spending. Figure 7 shows prescription drugs decreasing as a proportion of the Medicaid budget in Massachusetts after 2002, while nationally, the proportion of Medicaid drug spending attributed to prescription drugs increased from 13 to 15 percent of Medicaid spending. As figure 8 shows (the most recent years for published national estimates), Massachusetts Medicaid per-enrollee spending for drugs and other non-durables increased an average of one percent annually in 2003 and 2004, compared to eight percent nationally.

The timing of the MassHealth Pharmacy program with respect to the implementation of Medicare D also lowered program costs. Under the “phased down state contribution” (“Clawback”) provision of the Medicare Modernization Act of 2003, states have been required to reimburse Medicare for dual eligible Medicaid beneficiaries’ drug spending. The amount of this payment for each state is calculated according to a formula based on 2003 per-beneficiary drug spending, trended forward according to national drug spending growth. Because MassHealth already had implemented programs to contain pharmacy costs prior to 2003, Massachusetts was one of only eight states whose Clawback payment calculation was estimated to be less than the state would have paid for drug coverage in the absence of Medicare Part D. A full description of this savings has been reported in detail.²¹

Implementation of the MassHealth Pharmacy Program

State Medicaid pharmacy cost control programs have not always been implemented with success. Concerns by patient and provider advocacy groups about clinical impacts, alone or in concert with industry concerns about profitability, have sometimes made the process contentious, litigious and slow. Massachusetts' effort provides a sharp counterexample. While the formulation of this policy is not the focus of this paper, it is worth noting that several community and patient stakeholder groups played an active role in developing and supporting the principles on which the pharmacy program is based. This may have helped set the stage for the success of the implementation process. While no major policy change that touches the lives and pocketbooks of thousands of people is likely to avoid all conflict, the implementation of the MassHealth Pharmacy program was managed with success along several important dimensions.

Two essential steps in the process were to ensure credibility around the clinical criteria that are used in drug coverage choices, and to maintain the credibility of the decision-making process. In both of these, the MassHealth Pharmacy program acted proactively and with sound political judgment. Minimizing and managing those conflicts once they arose was also integral to successful implementation.

Clinical dominance

As this report has already documented, the cost of pharmaceuticals has been growing at dramatic rates in Medicaid programs, and the development of drug management programs was an explicit government response to that reality. But for many, the budgetary mandate raised fears that cost containment might well be done to the detriment of poor, sick and elderly Medicaid beneficiaries. The stakeholders interviewed for this report shared those concerns at the outset of the program's implementation. While most accepted that program-wide cost containment was a practical necessity, many continued to believe that changes to prescribing practices could put certain vulnerable populations at risk.

The MassHealth Pharmacy program leadership was acutely aware of this concern. Interviews with the program staff also indicated that they were determined to avoid any danger of doing harm to beneficiaries. To this end, MassHealth set up its initial decision-making criteria to ensure that clinical considerations dominated financial ones. Potential for cost savings did influence the development of the drug list and what specific drugs were reviewed, but only clinical evidence played a role in the decision itself. This was meant to protect patients and to reassure stakeholders.

Many states have joined the Drug Effectiveness Review Project (DERP), an initiative based at Oregon Health and Science University that produces systematic literature reviews of drug efficacy and safety. It is designed to provide Medicaid departments with high-quality, unbiased clinical information to assist with public policy and decision-making. Participation in DERP also has the advantage of the credibility that a national program confers.²² Massachusetts chose a different model.

The Mass Health Pharmacy program decided to build a local process for making clinical choices. The levels of expertise available in the state, the extensive contacts of the program's leadership and the sophisticated and numerous community-based advocacy

networks suggested that the quality and credibility of local decisions would be high. The program leadership felt that this, combined with their emphasis on clinical criteria, was the best way to ensure the creditability of its policies.

Managing the process

By most standards, the MassHealth Pharmacy program's clinical process was generally inclusive. MassHealth officials invited representatives of patient and provider groups to participate in the process, thereby serving both substantive and political goals. While invitations to local experts may have served primarily to guarantee credible clinical input, the invitation to patient advocacy and providers also helped obtain buy-in.

Most stakeholders interviewed felt that MassHealth reached out to them and invited their participation. Some recalled that they had to be proactive in order to have their views heard. However, even those who reported that they had to advocate to be part of the process felt that the program was responsive once they asked to be included.

This outreach was an intentional strategy on the part of MassHealth leadership. The experience of Michigan in attempting to implement a Medicaid drug list was widely known by the time Massachusetts began its implementation, and it served as a cautionary tale. In Michigan, an attempt to start the program quickly led to most decision-making being conducted without outside consultations. Additionally, all categories of drugs and program elements were put into place at once. Numerous operational problems emerged. These were attributed, in one report, to the rapidity of implementation and the lack of investment in administrative capacity.²³ It also reflected poor communication with the provider community. In addition, the stakeholder community, especially the mental health provider and advocacy community, responded very negatively. They formed alliances with the pharmaceutical industry, which filed several law suits. All of the law suits ultimately failed, but the state of Michigan paid a high political and operational price and the process came under strong criticism.

The MassHealth Pharmacy program decided that inclusion and consultation during implementation was preferable to conflict at a later point. The only major exception to this strategy was the exclusion of pharmaceutical companies themselves. This restriction on participation by representatives of the pharmaceutical industry was similar to that of the Drug Effectiveness Review Program (DERP). While it appears that some meetings occurred between MassHealth officials and representatives of the pharmaceutical companies, these meetings seem to have yielded little, and manufacturers were not invited to participate in review processes. Indeed, decisions regarding both the process of review and the decision not to seek supplemental rebates appear to have been effective in reinforcing the reputation of the process among local stakeholders.

At the same time, this inclusive system was structured to make certain that all participants played by the same professional rules. Stakeholders were invited to send representatives to review clinical evidence, but the representative at the meetings was required to have clinical expertise. This reinforced the primacy of clinical criteria, and effectively required stakeholders to present their positions in terms of clinical impacts.

When first implementing a Medicaid drug list, the question of where to start inevitably arises. One strategy is to address as many issues at the beginning as possible. This maximizes savings in the short run and, perhaps, gets all outstanding issues resolved quickly. This was the Michigan model noted earlier, and its failure may explain, in part, Massachusetts' very different approach.

In one sense, the Massachusetts experience did not deviate greatly from approaches in other states. Several clinical review boards were established, and they focused on those categories of medications where large savings seemed possible. However, the Massachusetts plan sequenced these decisions to ensure that only a manageable number of issues arose at once (see Table 1). Moreover, the program seems to have understood that clinical consensus was needed not only for technically sound decisions, but for politically practical ones. On issues such as minimizing polypharmacy and substitution of brand drugs for therapeutic equivalent generics, consensus was readily obtainable. This approach could be applied to many drug categories with minimal disagreement.

However, in some categories of medications, consensus proved unobtainable. This was particularly true for certain medications used to treat mental health and behavior health disorders. Difficulties also arose in other areas such as pain medication and treatment for epilepsy. Mental health medications were, and remain, among the most costly category of outpatient drugs for the Medicaid program overall, and thus, provide some of the most attractive areas for savings. Of the six medications seen early in the implementation stage (prior to 2003) to have the potential for cost savings in excess of \$10 million, three were related to the treatment of mental/behavioral health disorders. Two of these were dropped from the prior authorization lists explicitly because of “fierce stakeholder resistance” (MassHealth internal memo). A pain medication was dropped from restriction because patient advocates felt that the alternative medication for the condition (methadone) carried a social stigma that would adversely affect patients. Two other drugs in this group were not placed under prior authorization based solely on a clinical input from the expert review groups. One medication within this group of ten drugs was approved. Among this set of six medications, resistance from stakeholders persuaded MassHealth to forgo what they estimated to be \$95.3 million in savings.

The program’s initial plan to look for savings in those medications most costly to Medicaid clearly underestimated stakeholder resistance. Its emergence forced the leadership to face a stark, and explicitly political, choice. “Vehement stakeholder objections” threatened the implementation of the entire program and, to avoid this, “significant concessions” were made. These concessions were primarily around psychiatric drugs, although not entirely – as shown by the decision above regarding methadone, which is not strictly a mental health medication. While this level of resistance was not anticipated initially, the MassHealth program’s ability and willingness to respond to it was consistent with its general implementation strategy of managing conflict by controlled inclusion.

Inviting stakeholders into the clinical review process and structuring the process in purely clinical terms ensured that reservations, even opposition, could be encountered early and at points, within the clinical review process itself. This gave stakeholders a place to present reservations and an agreed-upon grounds – clinical impact – to use to formulate their objections. It also provided the program a forum and criteria to make concessions and change plans. This is an “action channel” in which accommodation could be made while minimizing the use of more contentious public forums. This is not to say that some use was not made of lobbying or more public statements, but the early decision to develop a system of clinical panels, and including stakeholders in them, provided a way of defusing conflict. MassHealth’s flexibility in this regard allowed it to pursue less contentious cost-saving strategies with substantial success, as outlined above.

Despite this largely successful attempt to manage conflict, there was some explicit political lobbying on the issue of policies aimed to control the costs of mental/behavioral health medications. Several years ago, the Massachusetts state legislature inserted a non-clinical decision-making point into what was, otherwise, formerly a purely clinical process. By legislative action (through a budget provision that has been reinstated each year), no additional mental health medication can be placed on a Medicaid prior authorization list without the approval of the Commissioner of Mental Health. This is a step separate from, and independent of, the clinical review panels. Providers and advocates pressed this requirement to ensure that an explicitly political decision-maker outside the oversight of the MassHealth Pharmacy program would have the final determination of restrictions on mental health medications. Advocates felt that this legislative provision gave them an avenue to protect their interests if MassHealth decides to revisit their policies regarding these medications. Officially, the program does not find this process particularly troublesome. In interviews, program leadership stated that they routinely coordinate relevant policies with the Massachusetts Department of Mental Health and that no operational conflicts arise. In a later section we consider future challenges for the program that might affect this mutually satisfactory compromise.

Stakeholder Views

By and large, stakeholders hold positive views of the implementation of the MassHealth Pharmacy program. Most feel that the program had proactively reached out to them and invited their participation. A minority was somewhat less positive regarding the accessibility of the process, and felt that they had to approach the program to make their views known. However, even these groups feel that were received and heard and expressed general satisfaction. For the advocacy community, the program's implementation has been generally acceptable to date.

Some of those most affected by MassHealth's operational aspects were critical of its implementation at the early stages, pointing out examples of administrative foul-ups and delays such as lost requests, erroneous refusals, and poor communications. But the early days of any program requiring hundreds of thousands of transactions will, almost inevitably, encounter "teething" problems. More importantly, those stakeholders interviewed who expressed complaints felt that the program has resolved most of them. They also felt that it was generally responsive to issues brought to their attention. In the Massachusetts context of active, experienced advocacy organizations, the absence of extensive criticisms of program implementation strongly implies a politically and operationally well-designed and executed effort.

A minimum of criticism can be treated (with adequate caution) as evidence of success in implementation. Using lack of consistent criticism by advocates as evidence of success in terms of clinical outcomes is more problematic. Nevertheless, it is worth noting that the interviews with representatives of more than one dozen stakeholder groups generated few "war stories" of patients being seriously adversely affected by the program. Some cases were presented, but most were seen as manageable or reflective of operational problems subsequently addressed. The MassHealth Pharmacy program is vulnerable to criticism on the grounds of inadequate evaluation of possible adverse clinical impacts, as are most such programs. However, in the Massachusetts environment of an aggressive, effective advocacy community, the absence of widespread complaint at least suggests that the program's cost cutting has not been achieved at high clinical cost to patients.

Evaluation of Clinical Impacts

Outside reviews of individual state Medicaid pharmacy cost control programs indicate that the overall clinical impacts of these programs have not been widely and systematically studied by independent observers.^{24,25} In particular, these reports have indicated that comprehensive, neutral evaluation of clinical impacts ought to be done. The reasoning is straightforward: attempts to control drug costs require changes in the way medications are used. Some of those changes might be clinically desirable, such as reducing polypharmacy and increased attention to drug management. Some might be clinically neutral, such as limiting payment levels for a drug or the substitution of true generic equivalents. However, regardless of program intentions, some policies might result in decreased access to appropriate medications. Only systematic outcomes research can determine if, or how frequently, access problems occur. Although Massachusetts avoided sweeping strategies adopted by some states, such as hard limits to the number of prescriptions dispensed, the program is nevertheless subject to the criticism above.

A complementary approach for detecting harm to patients is for a program to routinely conduct small-scale, pilot studies aimed at particularly vulnerable populations, or at classes of drugs that might be unduly sensitive to control policies. While not definitive, such work can be used to target more rigorous inquiries. The MassHealth Pharmacy program does conduct some of these preliminary inquiries. However, we could not determine the frequency of such studies, nor could we document their methodologies fully.

Further Implementation Challenges

Taken as a whole, the implementation strategy of the MassHealth Pharmacy program, particularly the MassHealth drug list, has been relatively successful. Costs appear to have been minimized to the extent practical in the current environment, political opposition largely neutralized and litigation avoided. The program has actively sought collaborations with some members of the advocacy community, and its implementation has been consistent with many of the recommendations expressed by advocates in the early stages of development, such as: the priority of clinical concerns in all cost-containment decisions; a shift to generic drugs; and provider education.²⁶ The program as implemented reflects a visible, credible commitment to sound clinical decisions, and a reasonably transparent and inclusive process to date. However, it also reflects an explicit choice to avoid confronting powerful stakeholders – in particular, mental health advocacy groups. Advocates in this area, along with some other patient groups, (notably epilepsy), opposed drug restriction policies on a variety of clinical grounds and a belief that their constituents were unusually vulnerable to negative health outcomes that could follow control efforts.

These groups, based on our interviews, remain adamantly opposed to many forms of prescribing control. They did not generalize their objections across all drug categories but, for the medications aimed at their patient communities, they expressed basic disagreement with any prior authorization policy. Terminologies differed but, in essence, they insisted that “provider prevails” was the only acceptable approach. That is, they could accept prior

²⁴Kaiser Commission on Medicaid and the Uninsured, *Case study: Florida’s Medicaid Prescription Drug Benefit*, February 2002.

²⁵Kaiser Commission on Medicaid and the Uninsured, *Case study: Michigan’s Medicaid Prescription Drug Benefit*, January 2003.

²⁶Greenberg J. The Facts on MassHealth: What it is. Why it works. Health Care For All Massachusetts. March 28, 2002. (Available at: www.hcfama.org/masshealthreport.html).

authorization policies only if any provider could over-ride that policy without outside review, based solely on his/her judgment that a given medication is appropriate. In effect, this rejects the central tenet of drug control policies based on outside clinical reviews using published clinical evidence. In this area, those advocates and providers interviewed believe that the vulnerability of this population, combined with the complexity of treating them, means that physicians must be allowed broad discretionary freedom.

As noted, psychiatric agents and anti-seizure medications are among the most costly category of non-specialty medications for Medicaid programs. If the several cost-saving policies in place are considered adequate, then the present compromise may well hold. However, if additional savings are to be pursued, this class of drugs is a major unrealized opportunity. Pursuing it may ignite conflicts that the program has adroitly avoided so far.

Several areas did not emerge through interviews as major implementation issues for MassHealth pharmacy, but may present challenges in the near future, considering the present pharmacy services environment and Medicaid policy. First, although MassHealth appears to have been largely successful in implementing programs to limit the unit cost of drugs, rising drug prices provide an ongoing pressure for cost-containment. The successful use of programs to promote use of generic drugs, as well as the policy of paying only the lowest price charged for generic drugs at any pharmacy, are strategies that skillfully use the market to assist in cost control. Nevertheless, price pressures may lead the program to re-evaluate early implementation decisions. As an example, the initial decision to limit supplemental rebates has been relaxed to some extent recently for certain drugs.

One component of the pharmacy benefit that promises to present a considerable challenge in the very near future is the rapidly-growing area of specialty drugs. This includes the newly emerging biopharmaceuticals, drugs that have no generic substitutes, require special handling and frequent monitoring, are often used for severely ill patients, and can cost over \$100,000 a year. These biotechnology drugs, initially used for cancer treatments and rare diseases, are now being used across a broader population and for chronic diseases such as rheumatoid arthritis and arthritis. Both public and private providers are now experiencing the difficulties in management of these high-cost treatments, often recommended for off-label (non-FDA-approved) conditions, and therefore difficult to control utilization. Medicaid programs, with limited budgets and an inability to require high patient cost-sharing as one means to manage specialty drug expenditures, are particularly vulnerable to the cost impact of these medications. The way in which MassHealth manages these medications will clearly be of interest to stakeholders.

Finally, MassHealth is facing several federal regulatory changes with implementation of the Deficit Reduction Act of 2005 (DRA). Through provisions of the DRA, Medicaid programs now have increased flexibility to design alternative benefit packages, increase patient cost-sharing, and restructure pharmacy pricing. Some states are considering program changes in response to DRA.²⁷ At the time interviews were conducted for this report, MassHealth program officials were assessing the impact of the new law, but no decisions had been made regarding changes to the current benefit. As of this writing, the pricing provisions of the DRA have been enjoined from proceeding by legal action brought on behalf of pharmacy providers.

Conclusion

The central goal of the MassHealth Pharmacy program in implementing the drug list and associated prescription drug controls is containing Medicaid drug costs. Based on the available data, it has been successful. But the central goal of this program is not its only goal. The program must also control costs without exposing beneficiaries to undue risks. Success in this dimension is more difficult to measure, and scientific research to do so has not been conducted in the state pharmacy program by outside independent entities. However, MassHealth's commitment to the goal of beneficiary safety appears to be sincere, and the program has instituted decision-making policies aimed at protecting patients from harm. Its drug review criteria gives predominance to clinical evidence, and allow prescribing restrictions only when confirmed by the clinical judgments of experts.

The MassHealth Pharmacy program has also taken pains to open its decision-making process to outside stakeholders. To participate, all of these stakeholders have been required to provide clinicians to represent their concerns. The sophisticated and extensive advocacy network in place in Massachusetts has had no apparent trouble responding to these terms of participation, and has provided clinical experts to provide input to the program as the drug list is updated and additional categories of medications are placed on restriction. The result has been a wide range of perspectives and the inclusion of view points that give primacy to patients' protection. This has played a major role in giving the program credibility with powerful stakeholders, and in minimizing conflict. The management of stakeholder input, the timing of program implementation, and the development of effective administrative systems, has combined to form a generally successful example of program implementation. Minimizing conflict has not meant avoiding it entirely, and the program has demonstrated flexibility in altering some of its plans to deal with resistance. Its hopes for changes in certain categories of drugs, notably for mental/behavioral health treatment, met strong resistance when proposed, and consensus on some cost control steps was impossible. In order to avoid compromising the implementation of the program as a whole, some of these issues have been set aside for now. This reflects a practical setting of priorities. We cannot say whether the issues that were initially set aside, or which of the additional issues mentioned earlier, will emerge to challenge the consensus the program has built, but the political success of the program to date gives some grounds for optimism.

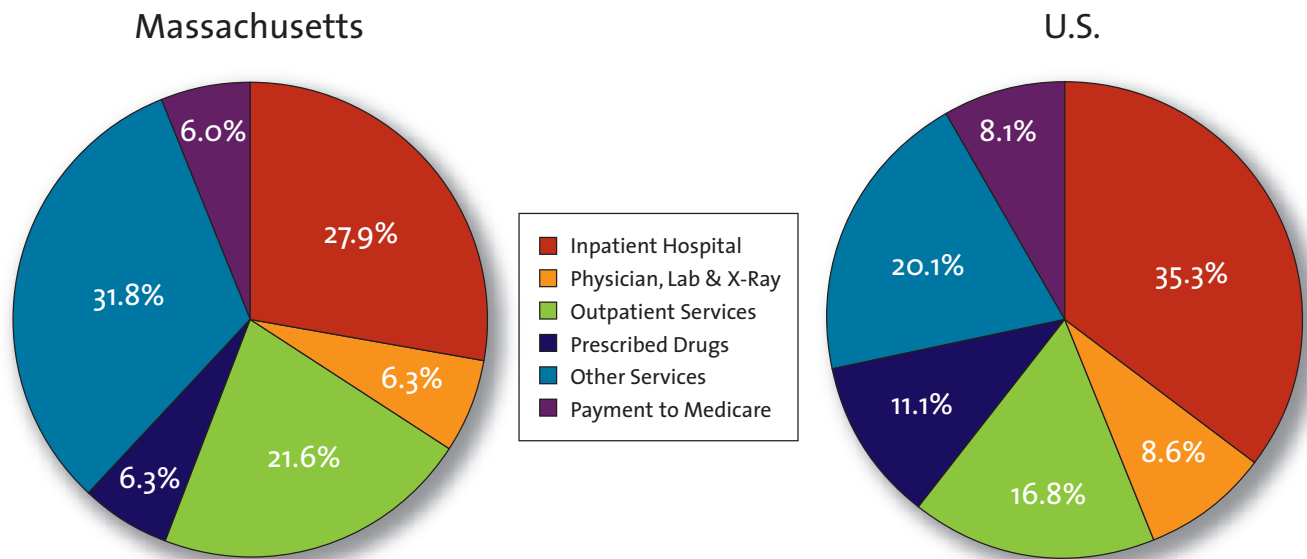
Table 1: MassHealth Drug List initial implementation timeline

Date	Drug class implemented
November 2001	Program regulations revised (130CMR 406.400), requiring prescribers to obtain prior authorization for brand drugs if generic approved equivalent available
November 2001-September 2002	Following therapeutic classes added to prior authorization drug list: Dermatological agents; Gonadotropin-releasing hormone analogs; Growth hormones; Hematologic agents; Immune globulins; Immunologic agents/ immunomodulators; Impotence agents; Central-acting muscle relaxants.
August 2002	Gastrointestinal agents - Histamine 2 antagonists, proton pump inhibitors
September 2002	Non-steroidal anti-inflammatory drugs (NSAIDs)
October 2002	Antihistamines
December 2002	Statins
March 2003	Triptans; Hypnotics; Antidepressants*
April 2003	Topical corticosteroids; Narcotic agonist analgesics
May 2003	Alpha-1 adrenergic blocking agents; Beta-adrenergic blocking agents; Calcium channel blocking agents; Renin-angiotensin system antagonist agents (ACE-inhibitors and ARBs)
June 2003	Intranasal corticosteroids; Oral antidiabetic agents; Respiratory inhalant products; Anticonvulsants*
July 2003	Atypical antipsychotic agents*
February 2005	Topical antifungal agents

* See Appendix 2 for special pharmacy management initiatives in these classes.

Source: MassHealth

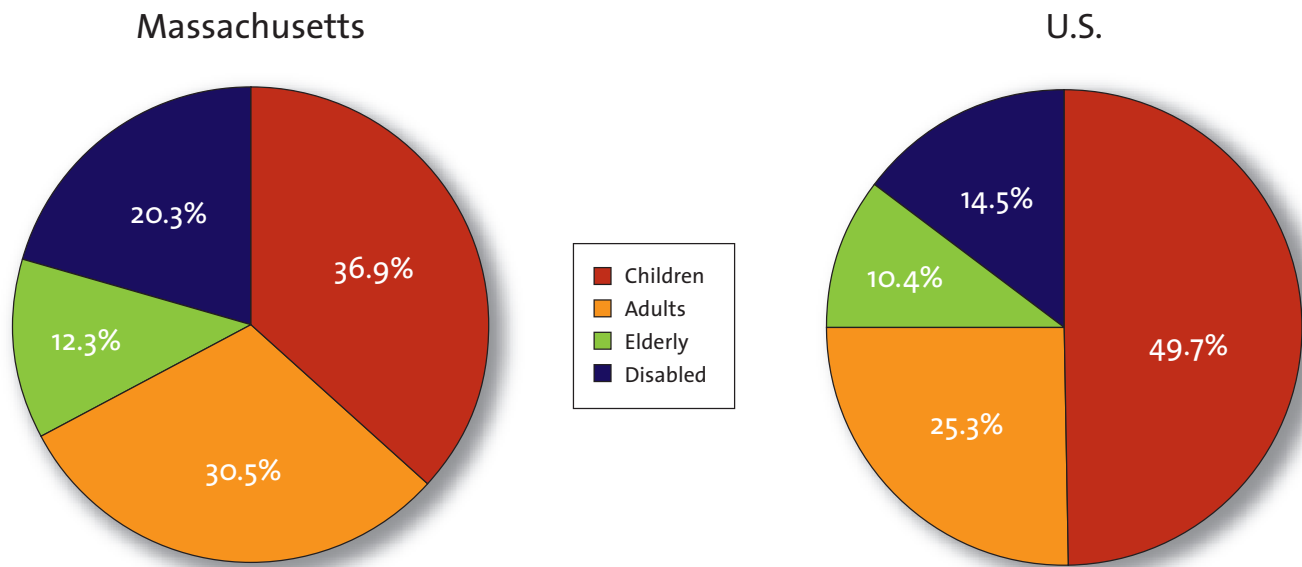
Figure 1: Prescription drugs as a percent of total acute care Medicaid non-managed care spending, Federal Fiscal Year 2007, Massachusetts and U.S. total for all states



Note: Fiscal year data span calendar years 2006 and 2007. Other services include, for example: dental, physical and occupational therapy, speech and hearing services, dentures, eyeglasses, etc.

Source: Kaiser Family Foundation StateHealthFacts.org (Accessed October 15, 2009)

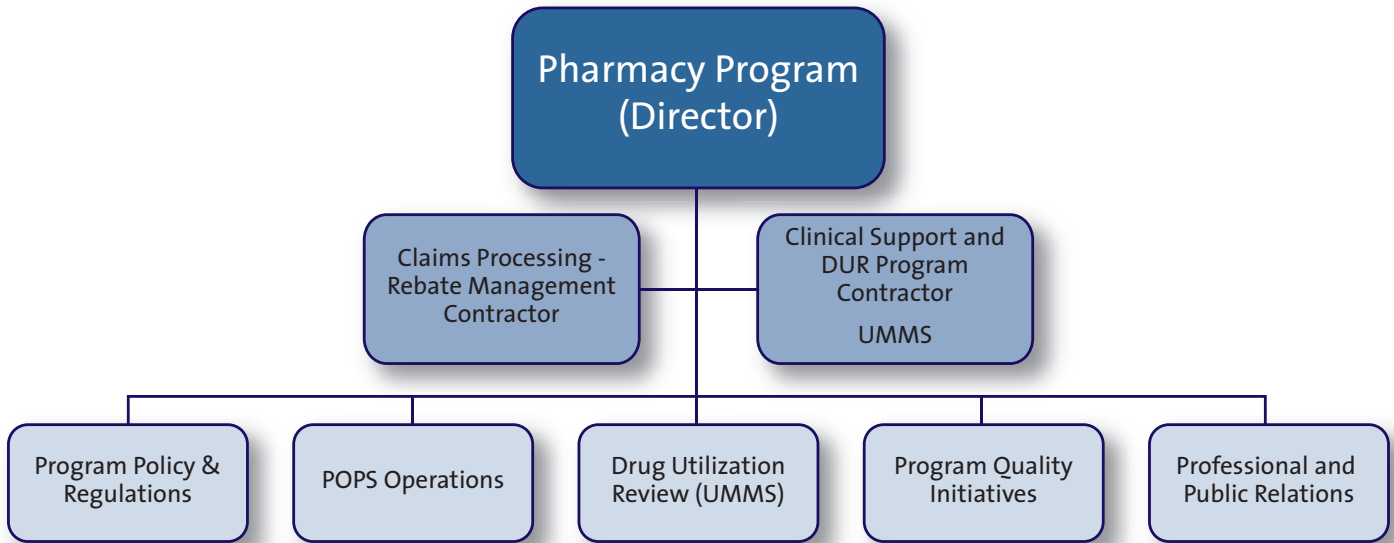
Figure 2: MassHealth and U.S. Medicaid program enrollment by eligibility category (includes managed care and fee-for-service), Federal Fiscal Year, 2006



Note: These data do not allow direct comparison between types of patients managed directly through the Medicaid program in Massachusetts and the U.S., as they do not take into account different levels of enrollment into managed care for Massachusetts and the U.S.

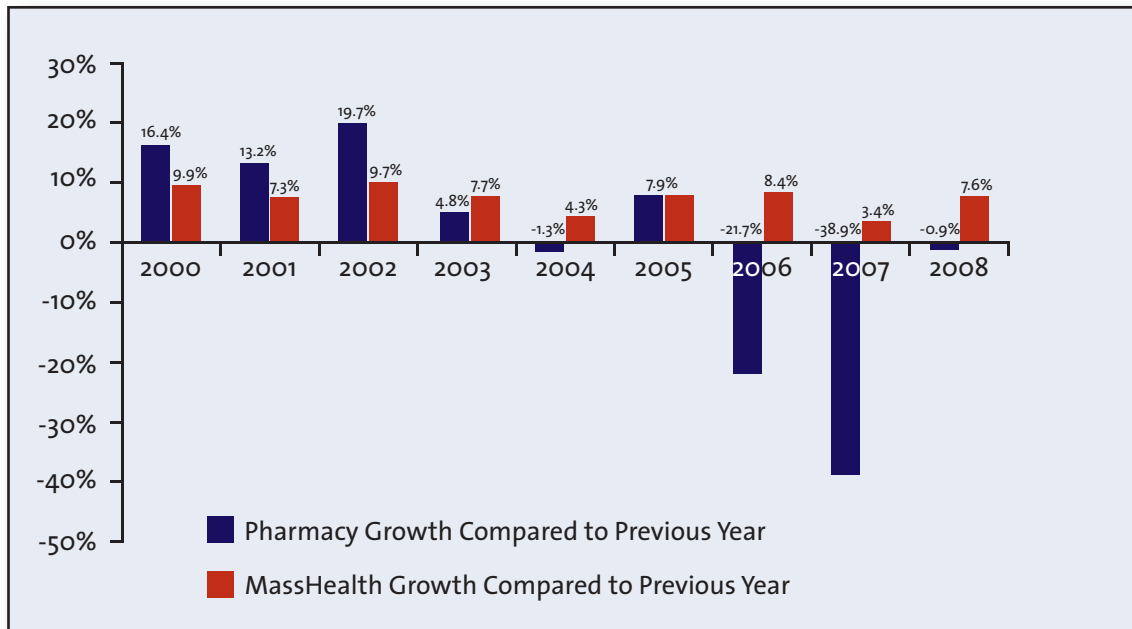
Source: Kaiser Family Foundation StateHealthFacts.org (Accessed October 15, 2009)

Figure 3: MassHealth Pharmacy program structure



Source: MassHealth

Figure 4: Aggregate trends in total spending growth for MassHealth overall versus MassHealth Pharmacy*

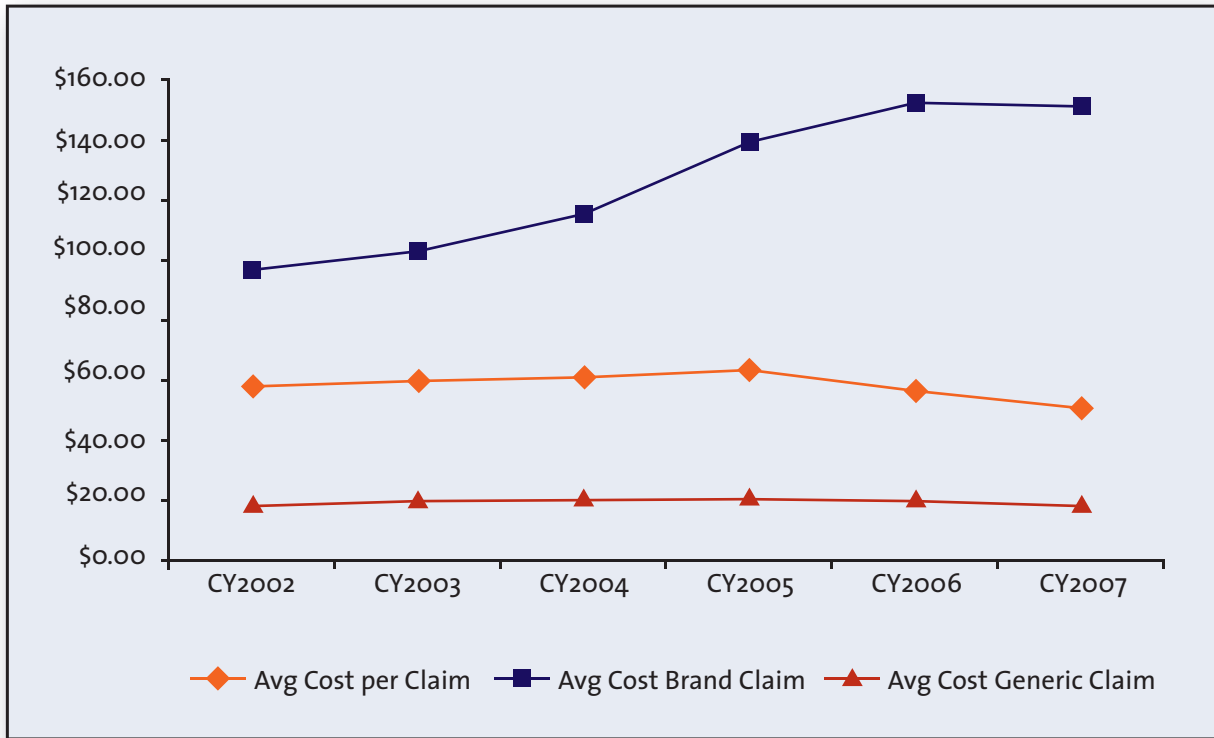


Note: Data were provided by MassHealth, and reflect overall program spending. MassHealth spending includes all members; pharmacy spending limited to non-managed care members, for which MassHealth has responsibility. Managed care increased as a proportion of total MassHealth membership from 18 percent to 34 percent between 2001-2008, (as MassHealth overall enrollment increased by nearly 22 percent), so over time, MassHealth became responsible for a smaller proportion of member drug costs by 2008.

Note: Starting in 2006, the Medicare drug benefit was implemented, and all dual eligible beneficiaries (this group makes up one-fifth of the MassHealth population, and are high drug utilizers) were moved from MassHealth coverage to private drug plans. The table above does not include “clawback” payments from the state to Medicare for maintenance of effort (see page 13 of this report).

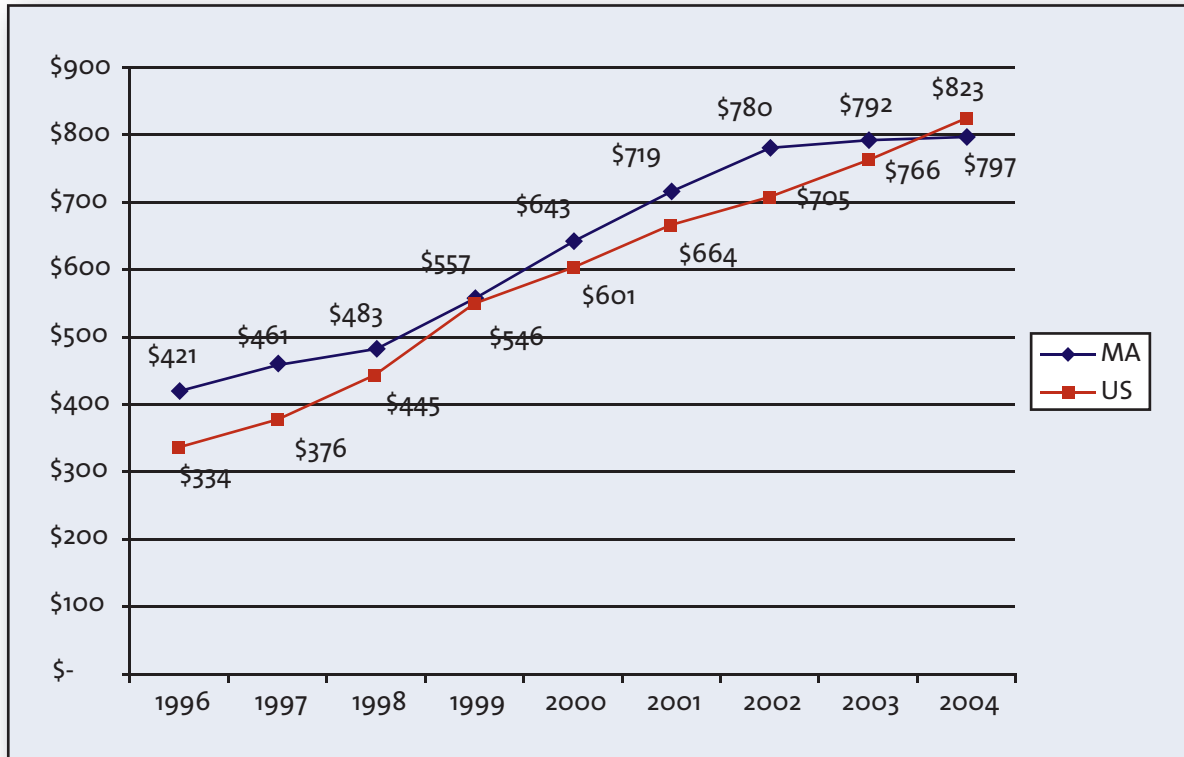
Source: MassHealth Pharmacy program

Figure 5: MassHealth trends in cost per prescription



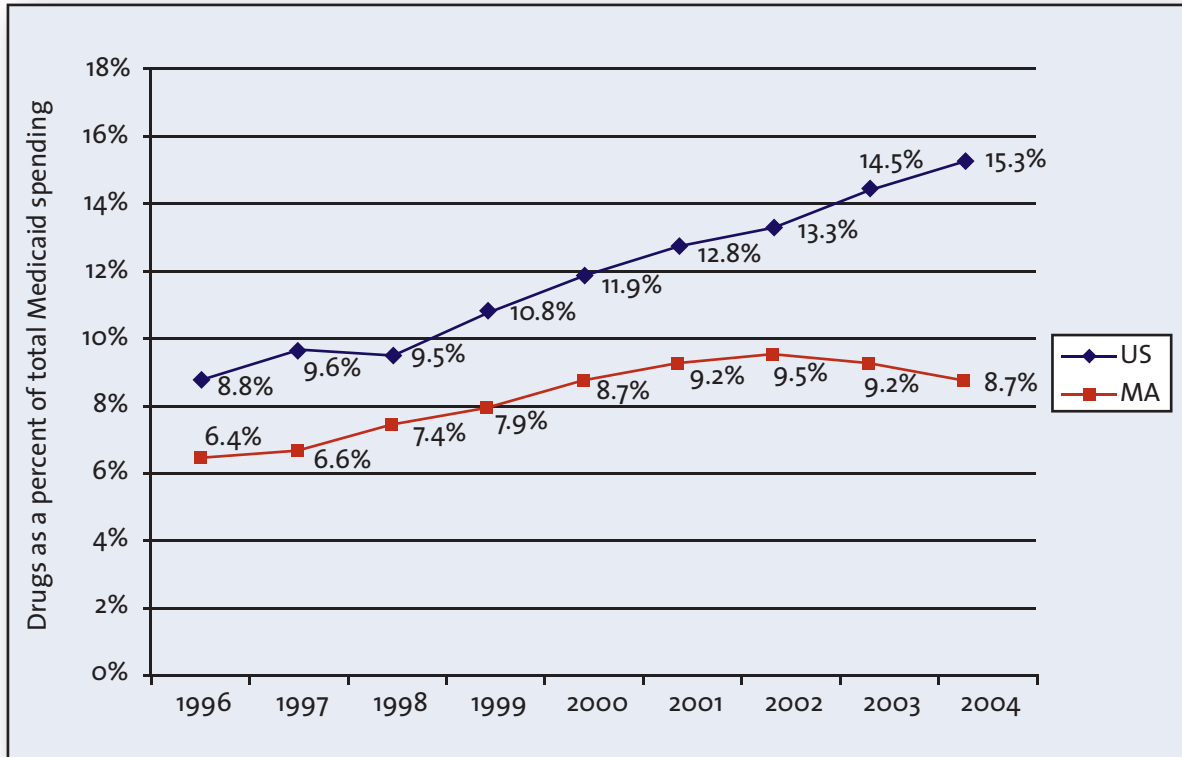
Source: MassHealth Pharmacy program

Figure 6: MassHealth Pharmacy trends in context: Medicaid annual spending per enrollee for drugs and other durables



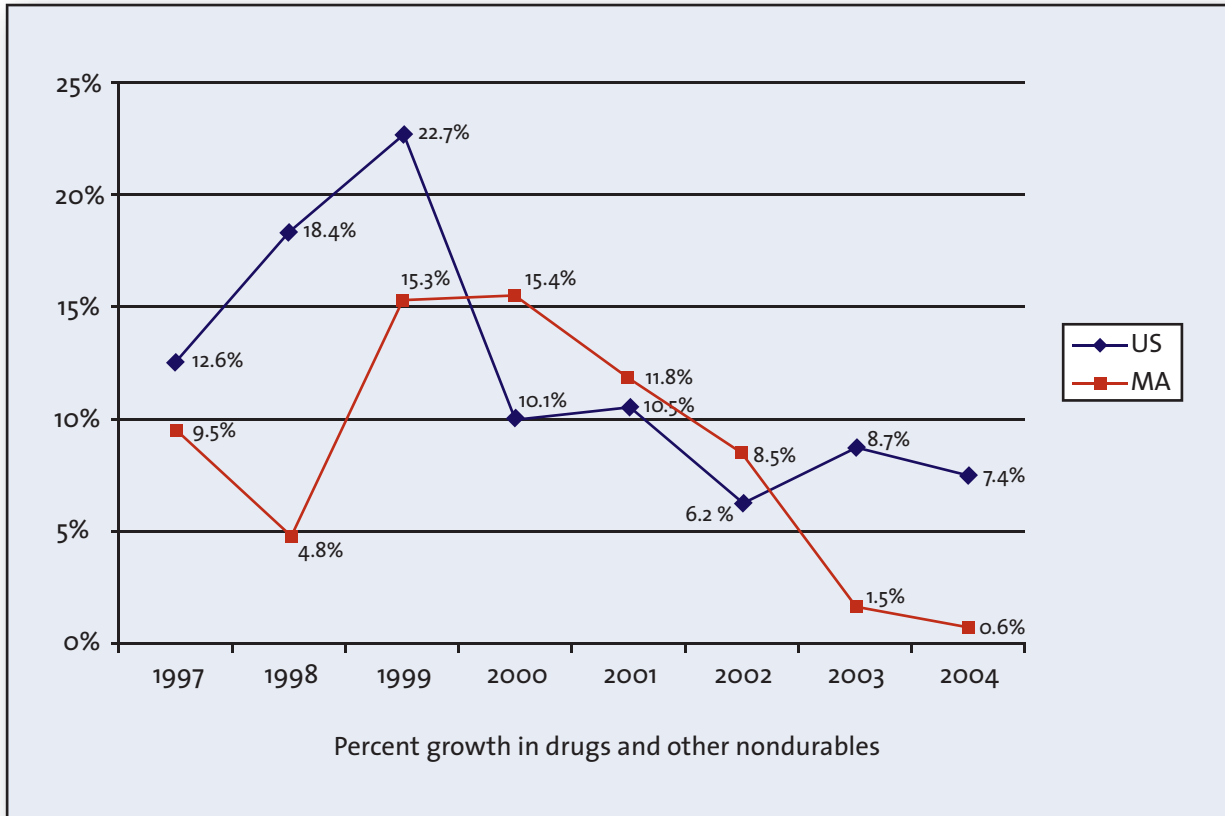
Source: CMS Statistical Supplement, CMS office of the Actuary September 2007
 (available at: <http://www.cms.hhs.gov/NationalHealthExpendData/>)

Figure 7: MassHealth Pharmacy trends in context: Prescription drug spending as a percent of total Medicaid program personal health spending



Source: CMS National Health Expenditures, Statistical Supplement 2007 Table 13.17, and state tables (available at: <http://www.cms.hhs.gov/NationalHealthExpendData/>).

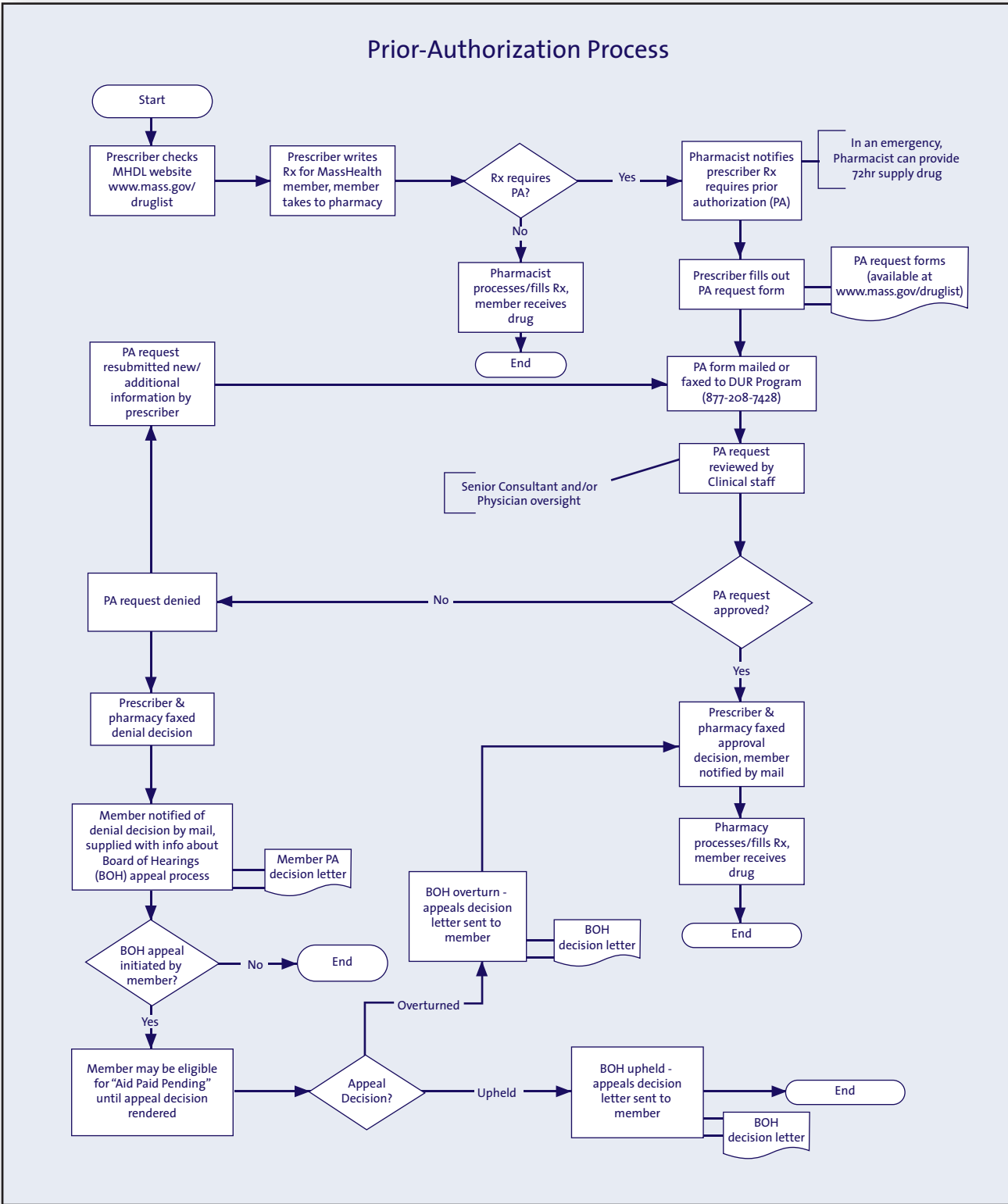
Figure 8: Growth in per enrollee spending on drugs and other medical non-durables, U.S. and Massachusetts



Source: CMS Statistical Supplement, CMS office of the Actuary September 2007
 (available at: <http://www.cms.hhs.gov/NationalHealthExpendData/>)

Appendix 1

MassHealth prior authorization process (figure provided by MassHealth)



Appendix 2

Review of selected therapeutic classes and pharmacy management initiatives implemented by MassHealth

Through Fall 2008, MassHealth had in place several initiatives for the management of particular therapeutic classes of drugs: anticonvulsants; antidepressants; antipsychotics; pain medications; and respiratory medications. As of January 2009, several of these classes have been removed from special initiative status, and guidance for prescribing in these classes is included under therapeutic classes, although management has not changed. Only pain management and atypical antipsychotic initiatives remain categorized as special initiatives. Descriptions of these initiatives, and drug list prescribing rules by therapeutic class, are published online by therapeutic class.²⁸ A brief review of several classes that are currently, or were recently special initiatives, suggests the following:

Current initiatives

Atypical Antipsychotics

This policy is much more complex than that of some other classes. Some drugs included in this category were a matter of stakeholder concerns and the compromises that were made to accommodate them. Most atypical antipsychotics are readily available, unless prescribed at high doses or in large quantities. MassHealth has established dosing limits for all of the atypical antipsychotics, with prior authorization required for any prescription above those limits. Prior authorization is also required for multi-drug therapy. There is a provision for generic clozapine and risperidone being available without prior authorization, and for several of the intramuscular injection medications being available without prior authorization. Some of the major atypical antipsychotics are available in oral disintegrating tablet forms, all of which require prior authorization. The form that needs to be submitted for PA is relatively open-ended in its request for information. With the information available for this report, it is more difficult to interpret true restrictiveness in this class compared to some of the other initiatives.

Pain medications

Various narcotic pain medications require prior authorization when they are prescribed above selected dose ranges. These dose limits are at pretty high levels: one could prescribe a lot of these low-cost narcotics before getting to the threshold for prior authorization. There is a suggested opioid treatment algorithm provided with the provider instructions, but how consistently this algorithm is implemented is not documented. A variety of brand-name narcotic medications require prior authorization, which appear to be reasonable according to independent expert clinician review.

Recent initiatives, current management practices

Anticonvulsant

Management in this drug class makes most of the commonly-used anti-seizure medications available without prior authorization, including several brand name products. This is consistent with a widespread belief among physicians, which has some support in the medical literature, that generic substitution is more difficult for anticonvulsants than for other medication classes, particularly as these medications have a relatively narrow therapeutic index. One drug in this category was dropped from the list of medications being considered for prior authorization after strong stakeholder objections. The list of medications restricted to prior authorization is small, and these would generally be considered second- or third-line medications for patients who cannot use other medications in the class. Overall, this approach targets a small number of medications and does not appear to impose undue clinical burdens, at least as the program details are made publicly

available on the MassHealth website. Recently, a number of commonly used anticonvulsants have become available generically, and MassHealth now requires prior authorization for the branded forms of these agents, while the generic forms can be prescribed without restriction. It remains to be seen whether there will be stakeholder objection to this generics-first policy.

Antidepressants

This class has a much more complex structure than do many other classes. All of the older agents (MAO inhibitors and tricyclics) are available without prior authorization, although they are unlikely to represent high volumes. The generic forms of most of the major antidepressants are available without prior authorization, other than high-dose fluoxetine and orally disintegrating mirtazapine. The bulk of brand-name selective serotonin reuptake inhibitors (SSRIs) require prior authorization, although the exact criteria are not listed. For three specific agents (Lexapro[®], Cymbalta[®], Effexor XR[®]) there is a separate level of prior authorization, specifying a need for documented treatment failure with two other agents before the targeted agents will be approved. There is a provision to “grandfather” patients who are established users of these three medications, for the life of the current prescription with refills. Finally, there is a provision in which prior authorization is required for apparent episodes of duplicative therapy with two SSRIs. This approach does appear to preserve easy access to commonly used and inexpensive generic SSRIs. In the early stages of implementation stakeholders expressed resistance to placing some of this category of drugs on prior authorization. Prior authorization forms on the MassHealth website provide relatively clear guidance on the documentation of multiple treatment failures.

Respiratory medications

Multiple inhaled medications are available without prior authorization, but these are mostly generic medications. Selected brand name or higher-cost inhaled medications require prior authorization. Of note, all of the long-acting beta-agonists require prior authorization. This is an interesting topic, since the role of long-acting beta-agonists is controversial at present. The FDA recently issued an alert about possible safety issues with use on long-acting beta-agonists. This seems an eminently reasonable policy and is probably the most clearly spelled out among these five initiatives. There are also three oral medications for asthma for which prior authorization is required, as well; for these, prior authorization is required if there is not clear evidence of asthma, which also seems reasonable.