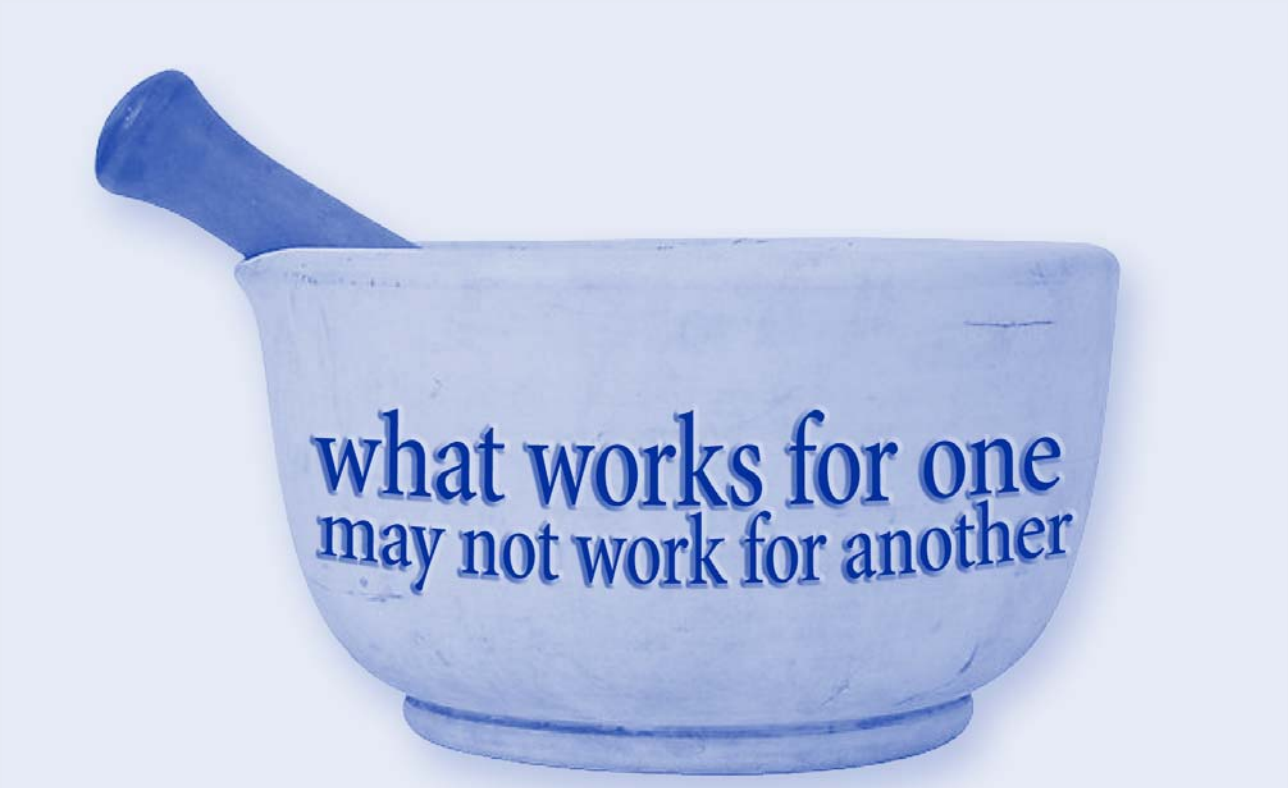
Medications and Mental Illnesses:

Preserving access and meeting the needs of patients, clinicians and taxpayers



Massachusetts Association for Mental Health, Inc.

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About Massachusetts Association for Mental Health, Inc. (MAMH)

Since 1913, MAMH has been recognized as an independent information resource within the mental health community. The National Institute of Mental Health's Outreach Partnership Program has designated MAMH as its Massachusetts partner for the dissemination of science based information on mental illnesses. MAMH is neither a trade association nor a provider of mental health services. It is a private non-profit Massachusetts corporation devoted to advocating community- based treatment and services for people with mental illnesses, and to the promotion of mental health. MAMH is an affiliate of the United Way of Massachusetts Bay, and is recognized by the Internal Revenue Service as a tax-exempt 501(c)(3) organization. For more information visit www.mamh.org or call 617-742-7452.

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I. Executive Summary

As a result of rising costs in health care coupled with lagging economic growth, states across the nation have been scrutinizing their respective Medicaid Programs to find savings. Because psychiatric drugs represent a large and growing portion of the total pharmacy benefits costs, a number of methods for controlling cost and utilization of these medications have been borrowed from the management of medications to treat other diseases. These include manufacturer discounts and rebates on particular drugs, prior authorization, use of preferred drug lists, fail first and step therapy policies, drug utilization review, and prescriber education.

Selecting the right medication for a person with mental illness is often a complex decision. Medications which work well on one person suffering with schizophrenia might well not work on another with the same illness. Moreover, adherence/compliance issues and efforts to improve outcomes often result in many medication changes in this population.

Medicaid directors and others have argued the very lack of interchangeability of psychiatric medicines (no one size fits all) that advocates have used to push for unrestricted access, justifies requiring clinicians to first prescribe a specific "preferred drug." If you don't know which medication will work, the argument proceeds, why not start with the least expensive drug?

Caught in the middle are those suffering from mental illnesses, and their family members. Their dignity and ability to live independently in the community depend, in part, upon reasonable access to medications. It is the promise of newer medications that lead people with mental illnesses and their families to embrace recovery in their struggle with debilitating conditions. Moreover, as we see reductions or static funding of community programs, psychotropic medications have become more important as the front line treatment for people with mental illnesses.

Because there is no national consensus on a "Best Practice" for integrating these competing demands, we believe achievement of the goal requires careful clinical judgment and thought as well as a process that encourages debate and inclusion of all stakeholders. Disabled adults, the elderly, children, and adolescents with mental illnesses or emotional disorders, are better protected if public policy in this area is developed thoughtfully in an open process which encourages participation and frank discussion, but which has as its goal, consensus among all stakeholders.

In addition to an inclusive policy development process, it is critical that clinical judgments form the underpinnings of all policy decisions. If Massachusetts were to adopt a "prior approval" process, it must be clinically driven and based upon the best available clinical judgment and scientific evidence.

It is also important that in developing policy in this area to take special note of children and adolescents with emotional disorders. The impact of medications on this population is different from that of adults. Psychiatrists actively engaged in the treatment of children and adolescents should be included on all advisory panels, committees or other groups examining policies in this area. The clinical and social consequences to a child or adolescent who is denied access to medications, or who is prescribed the wrong medication or who needs to change medications are different from and more serious than those faced by adults and seniors.

Two significant events on the national stage will impact the issues surrounding access to medications used in the treatment of mental illnesses:

- First, the results of the largest clinical study ever conducted on schizophrenia were published in the September 22, 2005 edition of the *New England Medical Journal*.[1] The National Institute of Health (NIH) funded study "Clinical Antipsychotic Trials in Intervention Effectiveness" (CATIE) compared treatments to discover both positive and negative impacts of antipsychotic medications. Approximately 1,600 patients were enrolled and followed for 18 months.
- Second, as a result of the Medicare Modernization Act (MMA), on January 1, 2006, all medications for dual eligible individuals (Medicare and Medicaid) will be covered through federal benefit and not through individual states. This is important, as all dually eligible individuals will for the first time have the same benefit across the country. While there was considerable concern that the access to medications through Medicare would be more restrictive than many states, the Center for Medicare and Medicaid Services (CMS) has stated it is requiring drug formularies to include **"all or substantially all"** drugs (including generic and older branded products) in the following categories: antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS. However, it appears that these medications may be placed on different tiers, resulting in higher co-pays.

At a minimum, we believe Massachusetts should not place restrictions on antidepressants and antipsychotics at least until the results of the CATIE study have been carefully analyzed **and** the new Medicare Part D benefit under the MMA has been implemented. Moreover, we believe the Commonwealth should engage in aggressive educational outreach to the prescribing community and that any proposed changes to the preferred drug list be subjected to a process which provides maximum clinical and other stakeholder input and which recognizes the importance of considering the impact of proposals on adult, children and adolescents.

To do otherwise would be to suggest that clinical judgment and scientific evidence are not important and would reinforce the suspicion that economics and not patient wellness is the driving influence. Moreover, since many of DMH's clients are "dually eligible" and will not be subjected to "prior approval," it makes little sense to travel a different path for those in MassHealth who are not Medicare eligible, at least until the full impact of MMA can be measured.

Finally, we have included recommendations designed to ensure that any prior approval process which is proposed is clinically driven with patient well being as its underpinning.

We believe policies developed with strong regard to clinical judgments, in a process that encourages debate, strives for consensus, considers the potential impact on child and adolescent patients as well as adults, and provides all participants with the best available clinical information will result in best case outcomes for Massachusetts and for those of its citizens with mental illnesses or emotional disorders.

II. Recommendations

Maintain a Public Health Framework in making future decisions.

Before extending "downstream" efforts that impact the doctor-patient relationship, "upstream" interventions that impact price, whether through supplemental rebates, reimportation or other bulk purchasing strategies, should be exhausted. In other words, primary prevention before secondary or tertiary prevention. Doctors and patients need education — to understand how the price of medication relates to the actual clinical impact. Continued educational efforts to promote prescriber awareness of the cost of medicines can be part of the solution.

Maintain and build upon the current emphasis on clinical judgement.

The Center for Medicare and Medicaid Services (CMS) cited Massachusetts and Missouri as leaders in a clinical approach towards reducing unnecessary polypharmacy. Also highlighted was a Texas initiative that utilizes a clinical algorithm to inform and structure physician decision making. The commonality of the three endeavors is **the focus on improving clinical care while attending to the pressing issue of cost.**

The Commonwealth can be justly proud of its work in the area of polypharmacy, which is likely to be replicated in other states. **Educational outreach to the prescribing community should be ongoing and a formal mechanism or procedures should be in place to allow for and encourage the free exchange of information between the prescribing community, Medicaid and the Department of Mental Health.** Quarterly or semi-annual meetings should be held and are preferable to simply setting aside a few minutes for public comment at the end of public meetings. We believe a more formal process could help to improve and quicken the timeframe from research to practice.

The Commissioner of the Department of the Mental Health should continue to have oversight authority over proposed restrictions on access to medications used in the treatment of mental illness.

We believe the continuation of DMH's oversight and authority in this area helps to ensure an emphasis on clinical judgment. Moreover, it is entirely consistent with the delegation of authority to DMH over Medicaid behavioral health issues.

The Department of Mental Health and Medicaid should formalize procedures and policies to ensure compliance with this provision of law with respect to all medications used in the treatment of mental illness and not just antipsychotics. The Department needs to create a formal process for exercising this authority.

The development of any policy is this area should be through a process that includes opportunities for the public and the prescribing community to have meaningful input.

- There are multiple stakeholders: physicians, including pediatricians, primary care, child, adolescent and adult psychiatrists, pharmacists, consumers, family members and advocates. MAMH believes an inclusive process, with fully engaged service recipients and users of the Medicaid system, is critical. An advisory group, convened to review the information gathered, can inform on ongoing policy developments. Missouri has a successful process for shared public policy, featuring an advisory group that advises policymakers on the effects of policy changes and their implementation. Missouri's advocates and patient representatives have worked in tandem with State officials to ensure that the Medicaid pool is zero sum. Difficult decisions relating to eligibility, benefits including pharmacy, and co-pays must be made, and continually assessed, in the most comprehensive and inclusive manner.

Include and consider the child and adolescent community in all policy development, reviews and implementation of policies because the impact in many instances will be different.

- Clinical standards for children and adolescents used in approval procedures should consider the growing body of knowledge for this age group, which may be different from adults. These differences can include length of trials, dosage ranges and other considerations. Above all, these standards must reflect flexibility to match the dynamic nature of the child's symptoms.

There is increased pressure for children and teens to return quickly to school after a hospitalization and to function well during the school day. In years past, a child might remain out for a few extra days or have a reduced course load. Today, with the pressures of MCAS and increased academic expectations, youngsters not in school are considered truant and those in school are expected to function well. Optimally, for those children who

require psychiatric medications, the meds help them attend school, focus, learn and manage their behaviors. However, child and adolescent advocates hear stories throughout the school year of youngsters who are sent home and barred from school because school authorities decided their medication was not working. Physicians treating such children need to be able to write a new prescription and have it filled speedily. Waits for approvals and paperwork are days missed from school.

Some adolescents do best with multiple medications. These are generally the most profoundly disturbed children and adolescents who are most often seen by the most experienced psychiatrists. This is similar to experienced obstetricians who take the highest risk cases. In these instances, it is often wise to trust the expertise of the prescriber.

Preserve current access to antipsychotics.

There should **not** be any prior approval restrictions placed on antipsychotic medications and consideration should be given to removing the current prior approval restrictions on antidepressants. While some will interpret the CATIE Study as concluding the newer (and more expensive) medications have no substantial advantage over the older medications, we believe CATIE demonstrates the importance of clinical judgment and flexibility in prescribing antipsychotics. **Overall, 74% of the patients in the study discontinued the medication they were assigned and the majority of patients in each group discontinued their assigned treatment owing to inefficacy or intolerable side effects or for other reasons.**

The following quote of Jeffrey Lieberman, M.D., CATIE's Principal Investigator and Chair of The Department of Psychiatry Columbia University and Director of the New York State Psychiatric Institute, is particularly instructive:

> "There is considerable variation in the therapeutic and side effects of antipsychotic medications. Doctors and patients must carefully evaluate the tradeoffs between efficacy and side effects in choosing an appropriate medication. What works for one person may not work for another." [2]

Additionally, the following excerpt from the Editorial appearing in the *New England Journal of Medicine* on the day it published the results of CATIE is likewise telling on the difficulty of measuring the effectiveness of medication when treating schizophrenia:

> "Schizophrenia is a chronic disability of mental and social function, with superimposed episodes of exacerbated psychotic symptoms. In addition to hallucinations and delusions, affected patients have characteristic neuropsychological difficulties, including problems in paying attention, learning new information, and recognizing social cues, such as the emotional meaning of facial expressions. Their social isolation, loss of sense of pleasure, inability to make decisions, and poor self-care forms a third symptom complex. Patients who carry the diagnosis of schizophrenia vary markedly in these various aspects of their illness. Efficacy [of a medication] is therefore difficult to measure." [3]

We believe the CATIE Study **demonstrates that in clinical terms there is no preferred drug.** Admittedly, there are preferred drugs in the economic sense, but to suggest everyone should be started on the same drug, unless prior approval is received, makes little clinical sense. Moreover, the legitimate interest in reviewing prescribing practices can be accomplished through educational outreach.

The decision by CMS to require inclusion of "all or substantially all" antipsychotic and antidepressant drugs in the new Medicare Part D Drug Benefit formularies suggests that the dually eligible in Massachusetts will not be subjected to "prior approval" and it makes little sense to travel a different path for those in MassHealth who are not Medicare eligible.

If a desire exists to "steer" the prescribing community towards a lower priced drug, it could be achieved by using tiered co-payments. But even here, it would be prudent to wait until additional information is available on the implementation of the Medicare Part D Benefit.

Proposed changes to the MassHealth Preferred Drug List for Medications used in the Treatment of Mental Illness should be reviewed in a clinically driven process that allows for maximum stakeholder input.

Some features or components that should be included in any proposal **to revise the Behavioral Health Care Preferred Drug List:**

- DMH should establish two clinical advisory groups one focusing on adult psychiatry, including seniors, and the other on children and adolescents to advise the Commissioner on any proposed changes. Members of this committee should include clinicians actively engaged in treating patients and prescribing medications.
- Either the Department of Mental Health (DMH) or the Office of Clinical Affairs in MassHealth (OCA) may initiate a request to revise the Behavioral Care Preferred Drug List.
- Designated personnel from DMH and OCA should meet to review the proposal. This review should be a data-driven analysis and include inspection of relevant utilization data and the current scientific literature related to the agent(s)under consideration.
- If DMH approval of the proposed change is sought, a draft of the revised protocol should be prepared and widely disseminated, including a posting on both the MassHealth and DMH websites.
- DMH will arrange for input from all concerned parties, including the Massachusetts Medical Society, Massachusetts Psychiatric Society, psychiatric nurse professionals and advocacy organizations regarding the proposed revision. The relevant utilization data and scientific literature will be available to stakeholders to assist in their commentary on the proposal. In this connection, while public hearings need not be required, there has to be an appropriate period of time in which clinicians, pharmacologists, and others can comment on the proposed revision. In brief, the goal is to create a comment period and process through which informed stakeholders can provide input.
- DMH, through its State Medical Director (SMD) should have ongoing regular meetings with stakeholders.
- Input from stakeholders will be considered and incorporated as appropriate into the proposal. After preliminary approval by both designated DMH and OCA staff, a final draft of the proposal to revise the Preferred Drug List will be forwarded to the DMH Commissioner.
- The Commissioner should present the proposed change to clinical advisory groups along with any revisions made as a result from stakeholder input and ask for recommendations.
- In the event the Commissioner approves the proposed change, including any revisions, it should be widely disseminated, including postings on the MassHealth and DMH websites along with the effective date and relevant explanatory information.
- There should be a prospective analysis of the impact of the change by MassHealth and DMH.
- The appeals process should be as it currently exists.

Recommendations relative to Prior Approval (PA)

We acknowledge the legitimacy of the economic concerns. If a number of medications are equally efficacious on the basis of evidence, it is reasonable to set up a **clinically driven tiered system of preferences** on the basis of those economic considerations. There should, however, be more than one medication available at any one tier.

Notwithstanding the above acknowledgment, current opposition to prior approval (PA) among clinicians, advocates, consumers and family members is strong and unyielding. We believe it is because PA in other states, as well as in Massachusetts, is not clinically driven. Experience in Massachusetts and elsewhere (as recounted by representatives from the prescribing community, consumers and family members) is that requests for prior approval almost always trigger requests for additional information and delay. This is how PA is designed to work, and this is why savings are realized. To say, PA does not mean denial of access, but simply requires a clinician to express his or her clinical judgment is to ignore how medical practice is conducted under managed care.

If a **clinically driven** prior approval system could be developed where requests are resolved expeditiously and decisions made solely on clinical factors (with physicians speaking with physicians) then the current opposition to such procedures would soften. In short, if patient well-being and not economics were the driving force, then we suspect the prescribing community, advocates, consumers and family members would respond accordingly.

To that end, we offer some features that we believe help make a PA process clinically and not economically driven.

- If in the opinion of a prescribing physician an emergency situation exists, including a situation in which a response to a prior authorization request is unavailable, the prescribed drug may be dispensed at the physician's discretion in an amount not to exceed a two week supply, and may be renewed for additional two week supplies until such time as the prior authorization process and appeals have been resolved. Any medication dispensed in said manner shall be eligible for full payment.
- If a medication becomes subject to prior approval, any patient receiving said medication may continue to receive it until the existing prescription expires, or for a period not to exceed six months, whichever is greater, without the need for prior approval.
- Prior approval should be an immediate and simple matter: For example, a web based automatic approval if the prescriber certifies either the patient had failed the preferred drug, or requires different medication for well-being.
- At a minimum, telephone, Internet, fax, or other electronically transmitted approval or denial should be made within twenty-four (24) hours of the request, unless the prescribing physician making the request indicates a longer period is acceptable. Routine requests for additional information as a method of avoiding denial without granting approval should be discouraged.
- There should be a Pharmacy and Therapeutic Advisory Committee to develop and implement improvements to the authorization process and such other matters as may be referred to it. The Committee should include physicians, including pediatricians, and adult and child psychiatrists licensed in Massachusetts and actively involved in the practice of medicine and psychiatry, pharmacists licensed to do business in Massachusetts and actively involved in the practice of pharmacy, and such other professionals and members selected to ensure the best possible clinical judgments and to maintain a strong clinical underpinning for any prior approval process which may be developed.

Consider pilot interventions – perhaps for one condition or for one population

Texas has demonstrated leadership in structuring clinical choices in the context of an algorithm. Here in Massachusetts, Harvard has an algorithm project that looks at decision making for psychiatrists. It may be that this interesting but untested imitative – structured decision making – can be part of the solution here in Massachusetts. Physicians here have long opposed any perceived restrictions on autonomy, but this is not a central feature of all algorithms. A process that involves professional communities and consumers and advocates may be able to drive a clinically based initiative as Massachusetts did with polypharmacy. It may be that putting this consideration in play will help to illuminate the severity of the issue to the professional community but also has the potential to forge a consensus on what elements of practice can be structured for the greater good of preserving access to medications.

A commitment to studying any policy interventions at both systems and clinical levels would be key towards keeping Massachusetts in a leadership position nationally on the issue.

III. Background and Overview

Across the Nation

Because of rising costs, particularly in the area of health care, coupled with lagging economic growth, states across the nation have been scrutinizing their respective Medicaid Programs to find savings wherever possible. Many states, alarmed at the rising rate of pharmacy expenditures, have initiated restrictions designed to "steer" the prescribing community away from the newer (typically more expensive) medications and to the older (and alleged by some to be less effective) medicines. These restrictive programs have ranged from "fail first" mechanisms – where a patient is required to fail on the cheaper and preferred drug before being allowed access to the prescribing physician's choice, to so-called "prior approval procedures" whereby a prescribing physician must obtain the prior approval of the state before prescribing any medication other than the one listed as "preferred".[4]

No one disputes selecting the right medication for a person with mental illness is often a complex decision. Medications which work well on one person suffering with schizophrenia might well not work on another with the same illness. Moreover, adherence/compliance issues and efforts to improve outcomes often result in many medication changes in this population.[5] Advocates, the prescribing community and pharmaceutical companies often argue that prescribing medication for a person with mental illness is a decision best left to the treating health care professional and not to a state panel interested in savings. This argument has carried the day in a number of states, which, either by Executive action or legislation, have exempted medications used to treat mental illness from any restrictive practices.

However, blanket exemptions from any restrictions on access, while cause for celebration among advocates, family members, clinicians and pharmaceuticals, do not address the underlying cost issues. Moreover, some have asserted that people with mental illnesses or emotional disorders, particularly children and adolescents, are often over medicated and therefore it is appropriate to place some restrictions or controls over the prescribing community. Still others have expressed the view that exempting medications for the treatment of mental illnesses from restrictions imposed on all other medications, including those for the treatment of AIDS, epilepsy, or cancer, is unfair and tantamount to asking the victims of one set of illnesses to subsidize the costs of providing medications to victims of mental illnesses. Some states have repealed or modified the blanket exemptions granted in previous years.[6]

Caught in the crosshairs of the debate and dilemma are those suffering from mental illnesses, and their family members. Their dignity and ability to live independently in the community depend, in part, upon reasonable access to medications. It is the promise of these newer medications that lead people with mental illnesses and their families to embrace recovery in their struggle with debilitating conditions. Moreover, as we see reductions or static funding of community programs for people with mental illness, psychotropic medications have become more important as the front line treatment for people with mental illnesses.

States, undeniably, have a right, if not an obligation, to examine spiraling costs and to consider efficiencies in all of its programs, including Medicaid. How to do this in the context of prescribing medications for people with mental illnesses, without "over managing" clinical practices, or denying patients the medications they need to live independent and quality lives is a complex but worthy goal.

Given that there is no national consensus on a "Best Practice" for integrating these competing demands, achievement of the goal requires careful clinical judgment and thought as well as a process that encourages debate and inclusion of all stakeholders.

In Massachusetts

Prior to the reorganization of the Executive Office of Health and Human Services (EOHHS), the Division of Medical Assistance (DMA) administered the Medicaid (MassHealth) Program.[7] DMA no longer exists. The Office of Medicaid (MassHealth) within EOHHS assumed its principal functions. The Office of Clinical Affairs (OCA) within MassHealth oversees the MassHealth Drug List.

In 2001, DMA and the Massachusetts Department of Mental Health (DMH) collaborated to initiate an educational outreach effort targeted at polypharmacy.[8] Cost and quality of care issues arise with the use of multiple prescriptions. The initiative was pursued as an educational outreach alternative to imposing restrictions on access. A clinical work group, including psychopharmachologists, representatives from the Massachusetts Psychiatric Society, DMH, DMA, the state Pharmacy Program and the Alliance for the Mentally Ill examined Medicaid drug data. It revealed "more than 2,200 adults received more than one atypical antipsychotic at a time for more than 60 days, at a cost of $24 Million; that almost 5,000 Medicaid recipients were taking more than one selective serotonin reuptake inhibitor for more than 60 days, at a cost of more than $4.5 million; and that more than 1,100 MassHealth recipients were receiving five or more psychiatric medications in January 2002, often from multiple prescribers."[9]

In response to this data, the Medicaid program conducted outreach to prescribers about the costs of these prescribing patterns as well as the threat escalating prescription costs posed to preserving access to these medications. In addition, physicians who routinely use polypharmacy approaches were identified and targeted for educational outreach. The estimated cost saving in psychiatric drug use was $10 Million.[10]

The Massachusetts polypharmacy approach was highlighted as innovative and a promising practice in an August 2004 paper from the Center for Medicare and Medicaid Services – "CMS: Psychotropic Medications: Addressing Costs without Restricting Access". (Hereinafter CMS Paper)[11]

While the polypharmacy approach continued, DMA began formulating "prior approval" procedures in an effort to control the rising costs of the MassHealth pharmacy program. Spending for prescription drugs is second to nursing homes and other institutional care, primarily for the elderly, as the largest category of Medicaid spending."[12] Not surprisingly, pharmaceutical companies and advocacy groups such as MAMH, NAMI-Massachusetts, and the Jonathan Cole Consumer Resource Center at McLean Hospital voiced opposition as well as concern that DMA was formulating its proposed new policy without sufficient public input and without outside or independent clinical review.

As the initial implementation date for the proposed prior approval policy (May 1, 2003) approached, substantive and procedural concerns about the process became more vocal and sustained.[13] MAMH testified before several legislative committees and met with House and Senate Leadership urging interventions ranging from a blanket exemption of all medications used for the treatment of mental illness to mandating public hearings, to requiring the approval of the Department of Mental Health (DMH) before any restrictions could be placed upon access to medications used in the treatment of mental illness.

Ultimately, both the House and Senate included in their respective budget proposals for Fiscal Year 2004, language requiring approval of the DMH before any restrictions could be placed upon access to medications used in the treatment of mental illness.[14] Shortly thereafter, the Division of Medical Assistance announced it was foregoing its plan because the expected savings "was not worth the health risks to an extremely fragile population."[15] According to published reports, **DMA emphasized its decision was based upon conversations with physicians and it is not necessarily the final word on the subject.**

> "Medicaid Medical Director … said doctors, not pharmaceutical representatives, persuaded the committee and state officials to change strategies on antipsychotics – but **she did not rule out further restrictions on antipsychotics in the future.**
>
> "Patients with schizophrenia 'are quite frail and vulnerable. The psychiatric community just isn't used to having this kind of intervention,' she said. **'We decided to go very slowly and not have disasters.'"**[16] (Emphasis added.)

The decision of DMA created a welcome respite. However, it is limited to anti-psychotic medications and does not, for example, apply to anti-depressants. Moreover, given the spiraling costs of medications and well as the increasing numbers of prospective MassHealth enrollees, it seems clear there will be continuing pressures to control expenditures either by reducing coverage, restricting access, eliminating benefits, initiating co-payments, or a combination of these and other measures.[17]

With the national interest in developing policy initiatives, Massachusetts has an opportunity to lead the nation in developing a policy that strikes an appropriate balance between competing and legitimate interests.

IV. Building Consensus: How to proceed, who to include

We believe disabled adults, children, and adolescents with mental illness or emotional disorders, are better protected if public policy in this area is developed thoughtfully in an open process which encourages participation and frank discussion, but which has as its goal, consensus among all stakeholders. This consensus will draw upon the Massachusetts experience to date – analyzing how the DMA/DMH approach, to date, has impacted patients, physicians, pharmacists and the cost to the system – and, ideally, develop the principles and guidelines for a best practice panel to address this issue.

Working with State policymakers and stakeholders, MAMH advocates the development of a process that ensures decisions formulated are clinically driven and focus on patient well being. Policies so developed will have the best likelihood to gain acceptance, reduce potential harms, and promote long-term fiscal solvency throughout all of MassHealth, and not just the pharmacy budget. Integral to this process are the many stakeholders who understand and daily experience the importance of psychiatric medications: consumers, family members, practitioners and professional societies. These parties have a vested interest to address the competing pressures that show no signs of abating: rising medication costs; the unique clinical challenges of patients on psychiatric medication; and State budgets under siege. None of these variables is likely to abate in the near term.

Moreover, we need to engage this issue over the long term, ultimately serving the interests of the Commonwealth and the users of the Medicaid system. This process will bring professional societies to the policy development table as well as the individuals and family members who are directly impacted by the decisions.

V. Some fundamental truths about psychiatric medications

A. Psychiatric medications are expensive

- If psychiatric medicines were inexpensive, this conversation and ensuing policy developments would not be occurring across the country. Efforts to reimport cheaper psychiatric medicines from neighboring Canada are but one example of the severity of the situation. Vermont has sued the Food and Drug Administration to allow it to legally re-import medications. Not surprisingly, the pharmaceutical industry actively opposes all efforts to reimport medications.
- Expenditures for antipsychotic medication have risen dramatically; the worldwide market for the compounds is now over $10 billion annually, primarily a result of the cost of the atypical antipsychotics.
- In the United States, state Medicaid agencies consistently list atypical antipsychotic medications as the first or second highest drug expense.

B. Psychiatric medications are an important part of treatment and recovery

- Although Medicaid pharmacy coverage is an **optional** service, all 50 States and the District of Columbia have opted to include it in their benefit packages. This evidences a consensus that recognizes the centrality of medications in treatment of psychiatric disability and symptom control.
- Managed care has to some extent made medications more central to the care system, as inpatient and outpatient services became more regulated and length of stay in hospitals dropped dramatically.[18]
- Medicaid continues to grow in terms of its importance to the mental health community. It is now the largest funder of mental health services and continues to grow.[19]

C. While the specific costs of medications can be measured, the fiscal impact on the system of care is difficult, if not impossible, to measure.

- In the United States, the current rate of growth of medications has increased at a double-digit rate in each of the last eight years. Yet changes in that "silo" in terms of adding or restricting medicines are difficult to measure as the system is complex and many variables are operating at once. For example, adding a new psychiatric compound may reduce inpatient expenses for one patient, reduce co-occurring alcohol use for another and increase medical complications for a third. The kind of system wide assessment of changes in one area and impact in another is virtually non-existent.[20]
- Studies have conclusively demonstrated that medications for psychiatric conditions not only produce a positive return to the individual in terms of symptom relief but also reduce impact on other expenses within the mental health system. While consistently reducing symptoms, psychiatric medications also reduce hospital costs and length of stay, lengthen time between manic episodes and psychotic episodes, reduce symptoms for obsessive compulsive disorder, and shorten the length and intensity of depressive episodes. Two recent studies have shown a substantial impact on the reduction of suicide: Lithium for bipolar disorder and Clozapine for schizophrenia. [21] Such qualitative outcomes cannot begin to be expressed in economic terms. Conversely, it is likely that a decrease in medication will increase cost in other health care areas.

D. While advances in medications provide the prescribing community multiple options, there is little guidance as to which medication will work best for a specific patient.

- The second-generation atypical antipsychotics (SGAs) have a different side effect profile from the first generation antipsychotics (FGAs) and have noteworthy differences among themselves. The side effects for the new compounds can include weight gain and or diabetes must now be weighed against NMS and tardive dyskinesia fro the FGAs, further complicating the risk assessment for each patient.[22] This supports an individualized approach in making prescribing decisions.
- In a 2004 review of SGAs versus FGAs (prior to CATIE), the authors concluded, "At present, the state of the art can only indicate a more favorable trend for SGAs in regard to improving medication adherence behavior, quality of life, and subjective tolerability.[23]
- The compounds have different neuroreceptor sites and side effect profiles. Medication selections for antipsychotic impact are made on prior response, maximal chance of adherence, and side effect profile.
- Currently no consistently accurate data is available for a physician to know which medicine will best help a patient prior to a trial. The 74% failure rate announced in the CATIE Study indicates that the clinician and patient should make the decision.
- Clinical experience has found variability in response and medication compliance in the match of individuals and compounds. Individual testimonials to one compound or another do not easily translate to other individuals.

E. Prescribing within an entitlement program for individuals with psychiatric disabilities or disorders further complicates the efforts of clinicians, program administrators and policy makers.

- Medicaid populations, which by definition include the disabled and poor, have a very different utilization of medications profile than those enrolled in private HMOs. There is a much higher incidence of mental disorders among the poor.
- In addition to deficits in cognition, insight and impulse, the psychiatric population is unique in that it is has significantly more co-existent medical disabilities.
- Psychiatric populations vary in many ways, but many diagnoses involve deficits in reality testing, cognition, executive functioning, and/or impulse control.[24] Individuals diagnosed with psychotic disorders have well documented rates of medication non-compliance that exceed other conditions.[25]
- For example, persons suffering from schizophrenia frequently (60%) have no awareness that they have an illness process (Amador), which likely drives much of the medication non-compliance.[26] This lack of genuine insight into the disease (anosgnosia) is embedded in the illness process and is not denial. The failure to recognize the presence of the illness is often the first sign of a patient deteriorating. Such special issues may have been the underpinnings of the recommendation of the Kaiser Family Foundation on Medicaid and the Uninsured that all psychiatric medicines be excluded from prior authorization, along with AIDS medicines.
- Compliance/adherence with medications is hard to measure but is a crucial variable in assessing impact of these treatments. While refills may serve as a proxy for adherence, this is far from a perfect correlation. Even as prescriptions are filled and re-filled, it is an unknown variable as to which patients are actually taking their medications.

VI. Public Health Framework in policy development: looking upstream before looking downstream

A principle many stakeholders endorse is that all due diligence must be done on pricing before interventions in the clinical encounter. In a public health framework if cost were the condition to be solved, then pricing would be upstream – primary or secondary interventions. Working at the level of the physician patient encounter is a tertiary prevention or downstream approach. While it seems clear total transparency of pricing should be obtained as a prerequisite to interventions at the clinical level, the fact is that has not happened. Moreover, upstream interventions are the prerogatives of the federal government. Some recent examples:

- After multiple procedural obstacles and delays, the Federal Government recently approved a plan in which States can form a purchasing pool to negotiate discounts on prescription drugs for Medicaid patients. Michigan, Vermont and South Carolina began these efforts more than a year ago, but were blocked by the Center for Medicare and Medicaid Services. Pharmaceutical companies also opposed the plan. South Carolina has quit the plan at this time. The purchasing States are Alaska, Michigan, Nevada, New Hampshire and Vermont. Current estimate of savings for 2004 is $12 million across the five States.
- Upstream interventions looking at cost are active though unpredictable – reimportation lawsuits and CMS's role in pricing compounds are two variables that need to be better understood.

VII. Common "downstream" interventions – Cost control in doctor patient encounter

A. Co-Pays

- The most common strategies used to motivate the consumer in HMO insurance plans are increases in co-pay and tiered co-pay, which encourages less expensive alternatives. Co-pays are based on the principle that the patient understands s/he has an illness and will contribute to the costs of medications. With serious mental illness, this insight is often missing and co-pays are restricted by Medicaid law to nominal amounts.
- New Mexico recently proposed a waiver with substantial co-pays for various services in the range of $10 – 25. However, such an approach may compound the problem for even small increases in co-pays can lead to non-compliance, thereby increasing other health utilization costs such as emergency room care for diabetic patients who may not be able to afford strict compliance with insulin and oral hypoglycemic therapies. [27]
- The philosophy of personal responsibility for utilizing public services has led many states, including Massachusetts, to increase co-pays. Current co-pays for people with psychiatric disorders have increased in Massachusetts from $.50 to $3.00. This is an important aspect of system change to understand in terms of its impact on patients and revenue generated. Again, it is important to emphasize that a philosophy of "personal responsibility" is more difficult to successfully extend to a situation where the illness impairs the insight of the individual to even acknowledge the illness.

B. Generic Drugs

- Massachusetts mandates generic substitution for all medications with an FDA A-B rating. Most but not all States have employed similar measures to reduce expenses while preserving choice. There is no question that such substitution provides a natural cost saving for many medications.
- While there is relatively little controversy about this policy, there are pockets of people taking Clozaril who are convinced the generic compound Clozapine is not as effective.
- CMS estimates that, on average, generics save 30% over brand name compounds for its discount drug users. (WSJ 9/16/04) The Congressional Budget Office calculates a 35-55% savings. There is no published estimate of how the generic conversion of more psychiatric medications will impact cost, but this may provide some relief for states.

C. Restriction of the Number of Prescriptions per person per month

- This is a utilitarian idea that forces doctors to decide which medications are crucial and compels an "instant triage" with the individual's medical needs being evaluated on a monthly basis. Obviously, there is cost in monthly patient visits. Moreover, good medical practice is the frequency of contact is driven by the condition of the patient and not by a system requiring monthly contacts.
- In New Hampshire in 1982, state Medicaid officials made the decision to restrict to three the number of medications a person could receive in a month. This meant doctors were triaging in the clinical encounter all an individual's troubles and picking the best three medicines for that person. One key result: the state was able to show a three-fold decrease in the cost of prescription medications. Had the analysis ended there, there may have been a lesson that this could be employed nationally. However, researchers also asked a question about the impact on other parts of the care system. This analysis showed a 17-fold increase in the cost of overall health care — mostly in Emergency Room and inpatient hospital days. So the effort failed at the one goal it was trying to achieve — to reduce costs to the system. There was no effort to improve care, and the effort to reduce costs was a failure. This model failed on clinical, ethical, and financial grounds. By restricting patient autonomy and physician choice, the state lost money. This is one of the clearest examples of poor public policy in terms of how to handle medication access and cost.[28]
- Alabama announced that effective July 1, 2004, it will restrict patients to four brand name medications total. It will also allow generics as needed, so as not to repeat the mistakes of New Hampshire. Many psychiatric medications are new and are therefore not generic. The atypical antipsychotics are all brand – not generic at this time (excepting clozapine which is now generic). Consequently, a complex patient with multiple medical concerns may be steered back to generic medicines, such as haloperidol. Alabama may be trying to address the issue of polypharmacy, but this is a very indirect way to go about that goal. The effort presumes that the action of all medications is equal, and that all medications will work the same for all people. This is a good assumption for medications like proton pump inhibitors for which the mechanism of action is precise and universal. Psychiatric medications do not translate well to this model.

D. Fail First

- Fail first generally requires the patient to fail on the preferred medication before authority is given to treat with a specific, often non-formulary medication. This approach restricts clinician and patient autonomy, which has been shown to lead to non-compliance. Fail first is being proposed for Tennessee this year. CMS in its first advisory to the states on Medication strategies stated that "fail first" and other very restrictive non-clinical interventions are not recommended.

E. Prior Authorization

- Prior authorization (PA) is the most commonly employed tool in Medicaid pharmacies but, unfortunately, is also one of the least well studied.
- PA results in "savings" because the experience in states utilizing this approach has been physicians, already pressured by the time constraints imposed by managed care, become frustrated either by the delay in obtaining approval, or the cumbersome process, and elect to prescribe the "preferred drug" instead of the medication they originally intended to prescribe. This, plus the fact the so-called "preferred drug" is usually the one whose manufacturer provided the largest discount, or "supplemental rebate" has lead advocates and others to refer to prior approval procedures as "prior denial."
- Prior authorization is complex in mental health medications, as service barriers of any kind can lead to patients not taking their medications. This is problematic from the ethical perspective of "first do no harm" but is likely to raise other societal costs as well, including emergency room/acute medical and psychiatric costs, and jail/prison criminal justice costs. Antipsychotic medications are protected across the board in many States due to enhanced understanding that 60% of people with schizophrenia have poor insight and that taking medications to assist with symptom reduction is not internally driven by the patient. People have trouble taking medications even when they feel sick, and the literature shows this is doubly true for people who do not see their illness as a problem to be solved.
- In April 2004 the Massachusetts DMA estimated that it had saved $95 million in its PA program in the preceding year while serving about 900,000 people or 15% of the Commonwealth's population. While 70% of all PA requests were approved, how many involved psychiatric medicines has not been made known.
- PA has a series of procedural protections built into it by Medicaid law. However, Michigan has demonstrated that a decision to severely restrict medications, even for people who are doing well on a regimen, when coupled with poor planning and no stakeholder involvement, triggers too much patient and public outrage. **The intervention in Michigan lasted less than two years and remains a teaching example of the necessity for painstaking process, sufficient timeline, involvement of stakeholders, and a scientific basis to effect change and successful decision-making.**
- Prior Authorization has been studied from a cost perspective in one state, Kentucky. There have been no studies of the clinical impact of PA. Kentucky Medicaid found that antipsychotic medications are the number one expense in their budget, similar to Massachusetts. They also noted that Zyprexa is the most expensive single agent, used in one-third of patients on antipsychotics and that it consumed half of the resources for the class of antipsychotics. Kentucky Medicaid placed a PA on new patients to be treated with Zyprexa. Patients who were already on the medication were exempt, as were patients who had been stabilized in hospitals on Zyprexa.
- The University of Kentucky, hired to study the impact of this change, found that the use of Zyprexa did go down but was replaced by other expensive atypical agents, such as Seroquel: "The PA appears to have some impact on Zyprexa utilization and costs since implementation in November 2002, with Zyprexa volume down about 8%. Looking at the entire class, however, both utilization and costs continue to increase. Comparing July 2003 to July 2004, overall class costs increased from $5.8 million to $6.9 million, while costs per script increased from $215 to $220."
- In sum, prior approval in Kentucky for Zyprexa did not reduce overall costs but it did reduce the "silo" of Zyprexa outlays within the pharmacy budget.[29] This is the best analysis of a psychiatric PA intervention to date, but it does not answer the question of how to reduce State outlays for medication. It shows that reducing one medication "squeezes the balloon" to another group of medications. This does not then generate a "best practice" recommendation. It also fails to help policymakers understand how to assess the impact on quality of care. The University of Kentucky noted:

  > "Given the short period of time since the PA initiation, more complex reviews such as patient outcomes are not yet practical on an aggregate basis."

- One health research noted the following with respect to prior approval restrictions, "It is sobering to realize that **if such policies were considered for a clinical study, the possible risks of reduced access to essential medications would likely result in a failure to obtain human-subject approval from most institutional review boards."**[30]

VIII. Downstream interventions that target prescribing behavior

A. Polypharmacy

- According to the National Association of State Mental Health Program Directors, the use of polypharmacy has grown rapidly over the past 10 years.[31] Missouri reports that 25% of acute care patients were using more than one antipsychotic agent (a smaller number were on three atypical antipsychotics); California reports an 11% polypharmacy rate with atypical antipsychotics.
- As noted above, the use of more than one atypical is frequently found among a minority of practitioners. In Massachusetts, a letter from the DMA Director to these frequent users of polypharmacy resulted in a significant reduction in the use of polypharmacy, with savings to the Commonwealth. This intervention aims to improve, or at least not impact, individual care while reducing untested and expensive interventions.

- In October 2002, Massachusetts DMA reported that more than 1,100 patients were on more than five psychiatric medications. The decision to require a PA for the sixth medication in Massachusetts was coupled with the offer of a consultation by a psychiatrist.
- Missouri also noted a substantial increase in polypharmacy. Its Departments of Mental Health and Medicaid together jointly elected to use a private company, Comprehensive Neuroscience Systems (CNS), to help them inform and educate their physicians about cost, and also to actively consult with and support/sanction the outlier prescribers. CNS is a clinical data gathering company that provides information to policymakers about what prescribers in the real world are doing with their patients in terms of prescriptions written. CNS does not set the parameters or edits; that is for State decision-makers to do. Missouri hired CNS to gather information about State practices so they could develop educational and monitoring strategies to promote better care. Missouri has used this intervention very well for the past year, and the rate of their cost increase for atypical antipsychotics has fallen from about 12% to about 4%, but clearly represents a net gain of cost. This idea meets the notion of improving clinical care while addressing medication costs.
- Both Missouri and Massachusetts have focused on this clinical area and have been identified as innovative by CMS. The key difference is Missouri uses a private company CNS and funding from the pharmaceutical industry to achieve it goals, while Massachusetts does similar interventions in house.
- It should be noted Massachusetts led the effort to improve clinical outcomes by addressing clinical practices that do not have an evidence base.[32] Massachusetts learned most physicians prescribed medications responsibly and it was a small percentage of doctors were responsible for the vast majority of uses of multiple expensive atypical antipsychotic agents. This was also true in Missouri: a small percentage of physicians use this untested and expensive practice regardless of patient presentation. In the absence of a scientific rationale and in the face of staggering costs, this is an area ripe for intervention. Yet it is important to recognize that there is no data to say what these aggressive prescribers are doing is wrong. They are aggressive prescribers who are outside the usual practice. They represent an area that may meet ethical and clinical concerns to improve care, and may save the system money.
- Massachusetts has an opportunity to advance the national conversation by publishing conclusions about the cost impact of this innovative approach.

B. Off -Label Use

- This strategy attempts to align prescribing with FDA approved indications. By restricting physician ability to prescribe medications off label, the thinking is to align science and prescribing behavior. This is complicated as the FDA is understandably conservative in applying its recommendations, and in some disciplines, such as child psychiatry, there are few areas where there are FDA indications for medications as it is difficult to recruit subjects in this population.
- Pennsylvania, Wisconsin, Minnesota and Utah require an ICD-9 diagnosis on each prescription for atypical antipsychotic medications. For example, the FDA label for Zyprexa includes indications for schizophrenia, monotherapy bipolar treatment, combination bipolar treatment (with lithium or valproate). Physicians frequently prescribe Zyprexa and other medications for psychoses not included above — dementia/ delirium and at times for PTSD, and for treatment refractory depression.
- It is impossible to assess the impact of these types of policies without a substantial commitment to a data-driven infrastructure. Off label use is common in medicine, particularly in children and adolescents, and is allowed to maximize patient and physician options.

C. Clinical Algorthyms—TMAP, PennMAP

- Texas has led the approach to ensure similar evidence driven care in its largely rural state by the use of structured decision-making or algo-rhythms. The Texas Medication Algorhythm project (TMAP) is utilized on a statewide basis.[33] The effort was cited by CMS along with Massachusetts and Missouri as one of the three states attending to clinical impact of medication decisions.
- TMAP has not yet had a published peer reviewed study showing either cost effectiveness or clinical care improvement but there is anecdotal support for the effort, and it is a practice that holds promise as its evidence is organized and studied. The interventions do not restrict physician choice per se, but rather recommend a series of decisions that all parties can follow and understand. Attachment two has the algorithm attached.
- Some states have employed restrictions on prescribing advertised as algorithms, and so this approach is met with skepticism. Yet the initiative in Texas may improve care for many, while allowing physicians to opt out for special circumstances. The absence of data that is published makes it difficult to recommend this practice as a best practice, but it one worth following and may be something for the Commonwealth to pilot in one area or with a subset of lower risk patients with many patient protections and physician autonomy built in.
- Pennsylvania adopted TMAP for its inpatient hospitals and the state medical director affirmed its impact on care and cost. But there is no peer-reviewed data, and this remains an untested public policy.

IX. Important national developments

A. Medicare Drug Bill for Dual Eligibles

- On January 1, 2006, all medications for dual eligible individuals (Medicare and Medicaid) will be covered through federal benefit and not through individual states. This is important as all dually eligible individuals will for the first time have the same benefit across the country. While there was considerable concern that the access to medications through Medicare would be more restrictive than many states, CMS has stated it is requiring drug formularies to include "all or substantially all" drugs (including generic and older branded products) in the following categories: anti-depressant, antipsychotics, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS. However, it appears that these medications may be placed on different tiers, resulting in higher co-pays.[34]
- Part D of the Medicaid drug coverage also promises to complicate the equation for State agencies. As Medicare assumes all coverage for dually eligible individuals (total in Massachusetts is 216,000 or 17% of the Medicaid population), states will not enjoy a windfall. Through complex "claw back" payments, the Congressional Budget Office notes that the law change may cost States more initially, with savings coming much later. The dual eligible population is sicker, more likely to have diabetes, and at higher risk than the general Medicaid population. Additionally, there is concern that a disenfranchised group will have difficulty making sense of the change. The Kaiser Family Foundation rated sorting through current multiple discount programs as "not easy" due to the "sheer volume of relevant data," noting that "the complexity of drug pricing can be overwhelming."[35]
- How a complex benefit change will impact people taking psychiatric medicines, but it is likely to have clinical consequences particularly in the transition for people on medicines not covered by the new benefit. This transition is one of the areas that will need continued monitoring as it has profound implications for this vulnerable population.

The CATIE Study

The Clinical Antipsychotic Trial of Effectiveness (CATIE) Study, funded by NIMH and headed by Jeffrey Lieberman, MD, is a multi-centered comparative study of the effectiveness of four antipsychotic compounds, both compared with each other and against an older medication. A total of 1493 patients with schizophrenia were recruited at 57 U.S. sites and randomly assigned one of the five medications being studied in the trial.[36] The results and conclusions of the study, published in the *New England Journal of Medicine* on September 22, 2005, were:

- Overall, 74% of the patients in the trail discontinued the study medication before 18 months, and the majority of patients in each group discontinued their assigned treatment owing to inefficacy or intolerable side effects or other reasons.
- Olanzapine (Zyprexa) was the most effective in terms of the rate of discontinuation.
- The efficacy of the first-generation antipsychotic agent perphenazine (Trilafon) appeared similar to that of the second-generation quetiapine (Seroquel), risperidone (Risperdal), and ziprasidone (Geodon).
- Olanzapine (Zyprexa) was associated with greater weight gain and increases in measures of glucose and lipid metabolism, exposing the patient to greater medical risk.

In general, media coverage following announcements of the results, focused on the point there appears to be little difference between the newer medications and the older ones. For example, the lead paragraph in the NY Times read:

> "A land-mark government-financed study that compared drugs used to treat schizophrenia has confirmed what may psychiatrists long suspected: newer drugs that are highly promoted and widely prescribed offer few - if any – benefits over older medications that sell for a fraction of the cost."[37]

As a result, some (perhaps many) Medicaid directors will cite CATIE as justification for requiring prescribers to first try an older medication or a less expensive one.

To the contrary, we believe a closer reading and analysis of the CATIE study compels the conclusion that psychiatrists need choices and flexibility in treating mental illness, that no one drug is effective for everybody, and patients often need to be switched from one medication to another. The importance of clinical judgment and flexibility are perhaps best espoused in the following quotes."

> 'There is considerable variation in the therapeutic and side effects of antipsychotic medications. Doctors and patients must carefully evaluate the tradeoffs between efficacy and side effects in choosing an appropriate medication. What works for one person may not work for another."
>
> – Jeffrey Lieberman, M.D., CATIE's Principal Investigator and Chair of the Department of Psychiatry Columbia University and Director of the New York State Psychiatric Institute.

"Thus the patient with schizophrenia and his or her doctor face difficult choices. Two drugs, olanzapine and clozapine, appear to be more effective than other agents. However, both drugs induce a significantly greater number of serious side effects. Even the most feared side effect of first-generation drugs, tardive dyskinesa, seems less troubling than potentially fatal metabolic problems. Does the apparently moderate increase in the efficacy of olanzapine and clozapine justify the use of these agents for treating patients? The answer to this question is a matter of clinical judgment and informed patient preference. Most clinicians offer patients several possibilities over the course of their illness." (Emphasis added.)[38]

C. Other Studies

The Oregon Center for Evidence Based Policy has issued its report on antipsychotics.[39] The report reviews the scant literature on "head to head" comparisons of medications, including the comparative efficacy, side effects, and subgroups for schizophrenia, bipolar disorder, dementia, autism, and ADHD. The report has been the subject of criticism from the American Psychiatric Association, the National Mental Health Association, and the National Alliance for the Mentally Ill. The center states it is incorporating feedback from these organizations into its work.

D. Recent FDA Warnings May Reduce Number of Prescriptions for Selected Psychiatric Medications

Since the first FDA warning in March 2004 on suicide risk for antidepressants in children, Medco reported an 18 percent decrease in scripts written for children and adolescents.[40] On September 14, 2004, the FDA made the decision to include a black box warning on all antidepressants, alerting to a rare but not insignificant risk of suicide. Many observers believe this will stop many pediatricians from prescribing the compound, as they lack the infrastructure expertise and time to adequately monitor the patients to whom they recommend the medication. While most likely substantially reducing access to treatment for many thousands of adolescents and children here in Massachusetts, with concomitant multiple negative consequences, from the narrow "silo" of medication expenses, however, it will show a saving to the system. Additional costs of school services, correctional time, increased medical visits and substance use and its sequelae are noteworthy but unknowable at this time. System analysis is required to understand what it means to add or subtract a medicine from the formulary, or even to substantially increase or reduce utilization.

E. Lawsuits against the FDA May Revive Reimportation as a Strategy

The FDA has taken a strong stand against reimportation, citing safety concerns. Yet multiple states and municipalities, including Minnesota, Vermont, Springfield and Boston, MA, have either taken an active role in promoting the strategy or are actively exploring the possibility. Vermont filed the first lawsuit against the FDA for prohibiting reimportation of medications. Other states are defying the FDA, and Canadian pharmacies are pursuing this market opportunity. Reimportation offers an average saving of about 40% on medications, more on some and less on others. Opening this avenue would transform the landscape dramatically, as reimportation directly attacks pricing without directly impacting clinical care.

X. Conclusion

To its credit, the Commonwealth has approached the issues with a strong emphasis on clinical judgments. Its educational outreach efforts in the area of polypharmacy have been cited with approval by the Center for Medicare and Medicaid Services. Moreover, the Legislature demonstrated both wisdom and restraint in providing the Department of Mental Health DMH), the Commonwealth's mental health authority, oversight in determining whether or not restrictions on access should be placed on medications used in the treatment of mental illness. This positioning of DMH gives the Commonwealth expertise and flexibility to respond as new information becomes available.

In short, Massachusetts has steered a rational and prudent course in addressing cost and access issues surrounding psychiatric medications for its Medicaid population. It should maintain this course and proceed in a fashion which emphasizes clinical judgment and which encourages stakeholder participation in policy development.

We believe policies developed with strong regard to clinical judgments, in a process that encourages debate, strives for consensus, considers the potential impact on child and adolescent patients as well as adults, including seniors, and provides all participants with the best available clinical information will result in the "best case" outcomes for Massachusetts and for those of its citizens with mental illnesses or emotional disorders.

End Notes

1. *The New England Journal of Medicine,* Vol. 353, No. 12, pp 1209-1223 (September 22, 2005)
2. NIMH Press Release http://www.nimh.nih.gov/press/catie_release.cfm
3. *N Engl J Med* 353:12 p 1287 (September 22, 2005)
4. The designation of a medication as "preferred" is a mixed clinical and economic decision. The initial grouping of certain medications as comparable or equivalent is, arguably, clinical, but the decision as to which becomes the "preferred drug" depends in large part upon which of the competing pharmaceuticals provides the largest discount or "supplemental rebate" to the state. *The Boston Globe,* June 12, 2003, Pg. 1 & A14).
5. Leslie and Rosenbeck *From Conventional to Atypical Antipsychotic and Back: Dynamic Processes in the Diffusion of New Medications, Am J. Psychiatry* 2002, 159:1534-1540.
6. See, e.g. New Hampshire
7. EOHHS is now the designated Medicaid Agency.
8. Polypharmacy is defined as the "use of two or more medications to treat the same condition, use of two or more drugs of the same chemical class, or use of two or more drugs with the same or similar pharmacological action to treat different conditions." Kingsbury, SJ, Yi, D, and Simpson, GM (2001) "Rational and Irrational Polypharmacy," Psychiatric Services, 52(8): 1033-1034, 1036.
9. Duckworth, K, and Hanson, A. (2002) "Using a Clinical and Evidence-Based Strategy to Preserve Access to Psychiatric Medications," Psychiatric Services, 53(10): 1231-32.
10. Ibid.
11. The paper can be downloaded at http://www.cms.hhs.gov/promisingpractices/mentalhealth.asp
12. *State Budget '03: The perfect Storm. . . Unleashed, Massachusetts Taxpayers Foundation, (*Feb. 2003) Pg. 21.
13. Criticism of the process (or lack thereof) lead to the formation of an *Ad Hoc* coalition of advocacy groups called AFORM (Advocates for Open Review of Medicaid). This group extended beyond behavioral health care and included groups focused on Epilepsy, Multiple Sclerosis, and Diabetes, to name a few.
14. The Governor vetoed the provision, but the House and Senate overrode the veto. The language reappeared in the FY 2005 budget, but this time it was not vetoed. **The Governor included the language in his House 1 budget submission for FY 2006.**
15. *The Boston Globe*, "Medicaid relents on a restriction" (June 3, 2003) pg. 1.
16. *The Boston Globe* (June 3, 2003) Pg. A5
17. MassHealth processes over 10,000 enrollment applications, and over 5 million health care claims each month. Report of the Legislative Task Force on Medicaid (April 2003).
18. Kaiser Family Foundation. www. kff.org/Medicaid/SCHIP
19. Ibid.
20. Kff.org Fact Sheet on Prescription Drug Trends, October 2004.
21. **For Lithium:** Lithium and Suicide Risk in Bipolar Disorder, Tondo L. Baldessarrini, R. and Hennen, J Primary Psychiatry 6(9) 1999, 51-56.
    For Clozapine: Meltzer, H. Suicide and Schizophrenia: Clozapine and the InterSept Study *Journal of Clinical Psychiatry,* 60 Supp 12, pp 47-50.
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24. Tasman, Kay, *Liebeman Psychiatry,* 2nd Edition, Wiley Publisher, May 2003.
25. Rettenbecher et al, Compliance in Schizophrenia Psychiatric Services September 2004.
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32. (See Duckworth and Hansen, "A Clinical and Evidence Based Approach to Preserving Access to Psychotropic Medications," *Psychiatric Services,* October 2002.)

33. Rush, et al. Medication Treatment of the Severely and Persistently Mentally Ill: the Texas Medication Algorithm Project, *Journal of Clinical Psychiatry,* 1999-60: 284-291.

34. www.cms.gov

35. Kff.org, Estimates of Medicare beneficiaries Out of Pocket Drug Spending in 2006, Publication No. 7201.

36. The older medication was Perphenazine (Trilafon); the newer medications were Olanzapine (Zyprexa), Quetiapine (Seroquel), Risperidone (Risperdal) and Ziprasidone (Geodon). Aripipazole (Abilify) was not approved by the FDA in time to be included in this phase of the study.

37. *New York Times,* September 20, 2005

38. Editorial – "The Choice of Antipsychotic Drugs for Schizophrenia", Robert Freedman, M.D. *The New England Journal of Medicine,* Vol. 353 No. 12, pg1286, 1287 (September 22, 2005)

39. McDonough MS, Peterson, K, Freeman M, Carson, S Drug Class Review on Atypical Antipsychotic Drugs Final Report http//www.oshu.edu/drugeffectiveness/reports/documents/AAP Final Report pdf.2004

40. *Philadelphia Inquirer,* Saturday, September 25, 2004.

✶ prior approval ✶ fail first ✶ generic only ✶ co-pays ✶ prior approval ✶ fail first ✶ generic only ✶ co-pays ✶ prior approval ✶ fail first ✶ generic only ✶ co-pays ✶ prior approval ✶ fail first ✶ generic only ✶ co-pays ✶ prior approval ✶ fail first ✶ generic only ✶ co-pays ✶ prior approval ✶ fail first ✶ generic only ✶

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