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December 29, 2005

Margaret Tomson
Chief Clerk of the House

Michael Marshall
Secretary of the Senate

RE: LEGISLATIVE REQUEST ON MENTAL HEALTH DRUGS

Dear Ms. Tomson and Mr. Marshall:

In response to the request from the 2005 legislative session to develop options for increasing the savings relative to psychotropic drugs while maintaining patient care quality pursuant to section 249A.20A relating to drugs prescribed for mental illness, the Medical Assistance Pharmaceutical and Therapeutics Committee (P&T Committee) formed a mental health subcommittee. The mental health subcommittee submitted their recommendations to the P&T Committee for review at the December 9, 2005 meeting. The final report is enclosed including an Executive Summary.

The P&T Committee is pleased to have the opportunity to present this report to you. Please do not hesitate to contact me if I may be of further assistance at (515) 725-1272 or spranger@ghsinc.com.

Sincerely,

Sandy Pranger

Sandy Pranger, R.Ph.
P&T Program Coordinator
IME Clinical Pharmacy Manager

cc: Governor Vilsack

Medical Assistance Pharmaceutical and Therapeutics Committee Report to the Iowa Legislature:

Options for increasing savings relative to psychotropic drugs, while maintaining patient care quality

December, 2005

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Executive Summary:

This report is in response to a request from the 2005 Iowa Legislative session asking the Medical Assistance Pharmaceutical and Therapeutics Committee (P&T committee) to "develop options for increasing the savings relative to psychotropic drugs, while maintaining patient care quality" for individuals receiving medications through Iowa Medicaid (Part 1).

The report summarizes key background information on patterns of utilization and cost of psychotropic medications within Iowa's Medicaid system (section II), and describes the process through which recommendations were developed (section III). Much of the work was done by a mental health subcommittee that was formed specifically to carry out this task. That subcommittee came up with a range of options for the full P&T committee to review. Each of those options is presented in this report (section IV). Finally, the recommendations that the P&T committee approved and chose to forward to the legislature are described (section V), and delineated below:

1) Eliminate the current exemption to the Preferred Drug List (PDL) process for the class of drugs known as "second generation antipsychotics" (SGAs).

2) Develop and implement prior authorization protocols for prolonged concomitant use of multiple mental health drugs within the same class.

3) Develop and implement prior authorization protocols for use of specific SGA medications outside of evidence-based dose ranges.

4) Implement a program to more aggressively target outliers, i.e., prescribers whose patterns of prescribing are consistently out of line with their peers, and with the existing evidence base.

Part I - Introduction:

This report is a response to the following legislative request from the 2005 legislative session:

> **(Legislative language)** *The medical assistance pharmaceutical and therapeutics committee established pursuant to section 249A.20A shall develop options for increasing the savings relative to psychotropic drugs, while maintaining patient care quality. This subsection shall not be construed to amend, modify, or repeal the exception provided pursuant to section 249A.20A relating to drugs prescribed for mental illness.[1] The committee shall submit a report of any options the committee recommends to the general assembly by January 1, 2006. Any options developed or recommended shall not be implemented without an affirmative action enacted by the general assembly.*

To carry out this work, the Medical Assistance Pharmaceutical and Therapeutics Committee (herein referred to as P&T committee) formed a mental health subcommittee. The task of the subcommittee was to discuss and investigate the pertinent issues and make recommendations to the full P &T committee by its December 2005 meeting, so that committee could then make optimally informed recommendations to the legislature by January 1, 2006.

Members of the mental health subcommittee were selected from 1) interested members of the P&T committee; 2) requests for representation from Iowa Medical Society, Iowa Psychiatric Society, the Iowa Association of Nurse Practitioners and the Iowa Physician Assistant Society. Membership of the sub-committee was as follows:

Member	Area of Clinical Expertise	Representing
Michael A. Flaum, MD (subcommittee chair)	Psychiatry	P & T Committee
Bruce Alexander, RPh, PharmD, BCPP	Pharmacy / Psychiatry	P & T Committee
Sherry Baze, CPNP, ARNP	Behavioral Pediatrics	Iowa Association of Nurse Practitioners
Matthew Osterhaus, RPh	Pharmacy	P & T Committee
Susan Purcell, RPh, CGP	Pharmacy	P & T Committee
Mark Purtle, MD	Internal Medicine	Iowa Medical Society
Don St. John, PA-C	Psychiatry	Iowa Physician Assistant Society
Kevin Took, MD	Psychiatry	Iowa Psychiatric Society

[1] "The "exemption" referred to in this legislative language and throughout this report refers to the following language in the initial enabling legislation for the PDL: *"With the exception of drugs prescribed for the treatment of human immunodeficiency virus or acquired immune deficiency syndrome, transplantation, or cancer and drugs prescribed for mental illness with the exception of drugs and drug compounds that do not have a significant variation in a therapeutic profile or side effect profile within a therapeutic class, prescribing and dispensing of prescription drugs not included on the preferred drug list shall be subject to prior authorization".* From Iowa Code 249A.20A

Part II – Background: Utilization and Costs of Mental Health Medications

Medication costs have been increasing dramatically across all health care systems over the past decade. In the past five years, medication costs for Iowa Medicaid have increased 82.5%. Drugs used primarily for mental health problems account for a significant and growing portion of these costs.

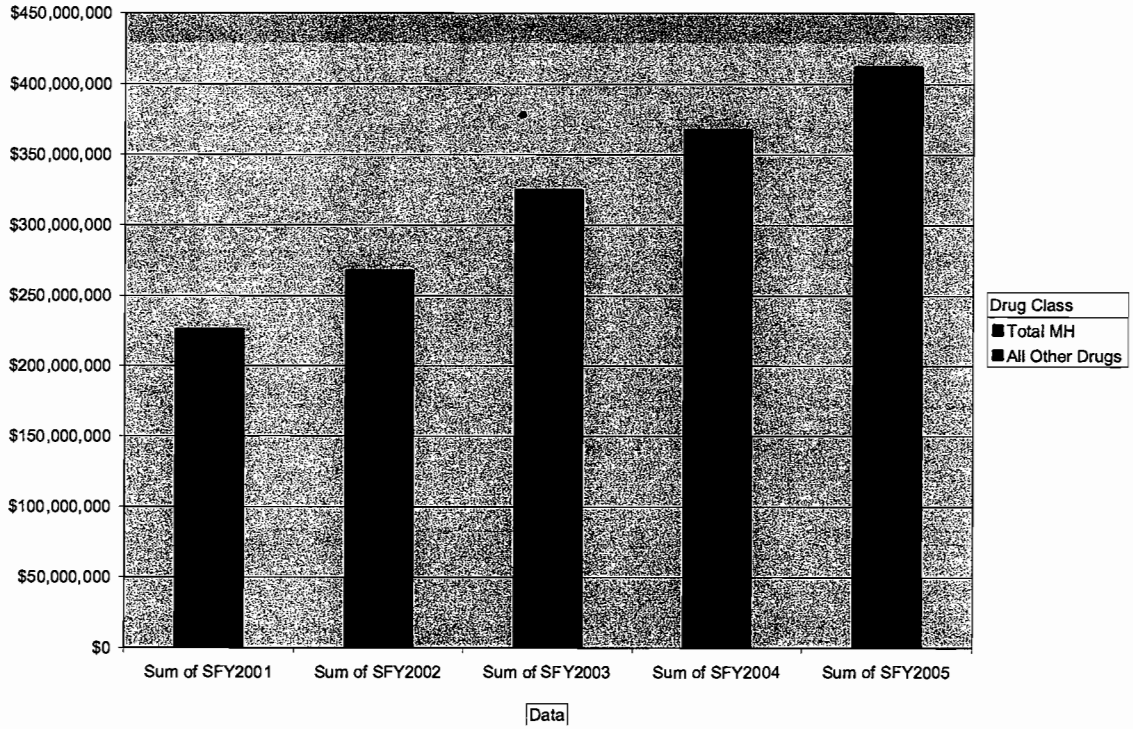


Figure 1: Total Drug Costs for Iowa Medicaid by Mental Health (MH) and All Other Classes

Drugs used primarily for mental health reasons accounted for 39% of all drug costs in 2005, up from 37% in 2001. It is anticipated that this percentage will increase significantly in FY2006 as the cost-savings of the PDL on other classes of drugs are further realized[2].

It is also important to recognize that these cost data do not include rebate discounts from the PDL. Thus the actual proportion of costs to the state of mental health drugs are underestimated in the data reported herein.

Another consideration is that when "dual eligibles" (i.e., those eligible for both Medicare and Medicaid) are removed from the data above, the proportion of MH drugs increases (to >44% as of SFY2005). Thus it is expected that once Medicare Part D becomes effective as of January 2006, MH drugs will account for a larger proportion of the overall Medicaid drug budget.

[2] SFY 2005 is from July 04 – June 05. The PDL was instituted mid-January 2005, and thus only a portion of its effects would be reflected in these data.

Figure 2 shows the costs of MH drugs, by class, over the past five years for Iowa Medicaid. Antipsychotics reflect the largest portion of the costs of MH drugs as a class. As such, a brief explanation of the changes in practice patterns regarding this class of drugs follows.

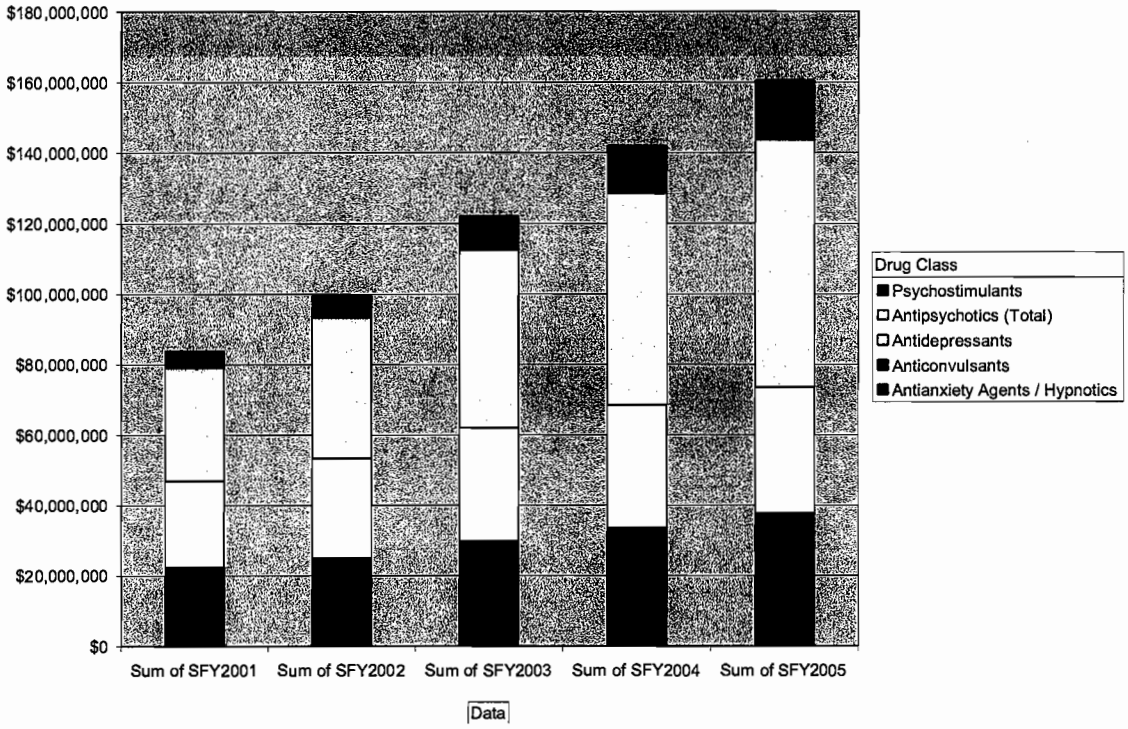


Figure 2: Costs by MH Drug Class

Introduction of "Second Generation Antipsychotics": The biggest change has involved the introduction and wide scale use of the so-called "atypical" or "second generation antipsychotics (SGAs)", distinguishing them from the "typical" or "first generation antipsychotics (FGAs)" that have been in wide use for the past half century. Clozapine / Clozaril®, FDA approved in the US in 1990 was the first SGA.[3] While shown to be superior in efficacy to FGAs, its side effect profile limited its widespread use. However, since the mid 1990's, five other SGAs have been introduced to the US market (Risperidone /Risperdal® 1994, Olanzapine / Zyprexa® 1996, Quetiapine / Seroquel® 1997, Ziprasidone /Geodon® 2001 and Aripiprazole / Abilify® 2002), and have essentially taken over the antipsychotic market (estimated to be at least 90% of all antipsychotic prescriptions). This is despite the fact that clozapine remains the only agent that has been consistently proven to be superior in efficacy to the FGAs. Each of the five other SGAs have at least equivalent efficacy to the FGAs, and what had been thought to be a better side effect profile (fewer extrapyramidal symptoms, including less tardive dyskinesia). However, over the past few years, the assumption that the side effect profile was clearly superior to FGAs is being reconsidered in light of other side effects of the SGAs (most notably higher rates of diabetes mellitus).

[3] NOTE: Throughout this report, the abbreviation **"SGA"** will be used to refer to the "atypical" or "second generation" antipsychotic medications, and **"FGA"** to the "typical" or "first generation" antipsychotics.

Costs: Each of the SGAs is quite expensive relative to the FGAs. For example, a month's supply of haloperidol, the most widely used FGA, costs approximately 5-10 dollars. The average monthly cost/claim for any first generation antipsychotic in SFY'05 for Iowa Medicaid was $36. A month's supply of any of the SGAs cost in the hundred's of dollars, ranging from ~ $100 – $1000 /month depending on dose, specific drug, and formulation. The average monthly cost/claim for SGAs in SFY '05 for Iowa Medicaid was $230.

Increased utilization and indications for SGAs: In addition to the markedly increased cost of this class of medications relative to their predecessors, they are being prescribed much more often. FGAs were used primarily for schizophrenia and related psychotic disorders, as well as, but to a lesser extent, behavioral problems in the context of dementia, delirium and other cognitive disturbances. However, beginning with olanzapine, several of the SGAs now have FDA indications for use in acute mania. Use of these drugs in bipolar disorder maintenance and prophylaxis is now commonplace thought based on few controlled trials. Further, the construct of bipolar disorder has broadened considerably over the past decade or so, with the increased acceptance of a milder form of the disorder, known as bipolar type II. While all of the trials and indications are directed at the more classic type of bipolar disorder (type I), clinicians have extrapolated the effectiveness of the SGAs in acute mania of BPAD type I to all areas of bipolar disorder. There is also increasing evidence of effectiveness of SGAs in behavioral problems in the context of mental retardation and dementia, as well as some evidence of effectiveness in conduct disorders, and their use in those populations has become widespread. In addition to these uses, it is increasingly common practice to use the most sedating of this class, quetiapine, in doses lower than recommended for any of its indicated uses, as a sleep aid.

Together these factors have led to a large increase in the use of this class of drugs, with a corresponding increase in costs, across virtually all health care systems. Figure 3 shows the costs to the Iowa Medicaid system over the past five years.

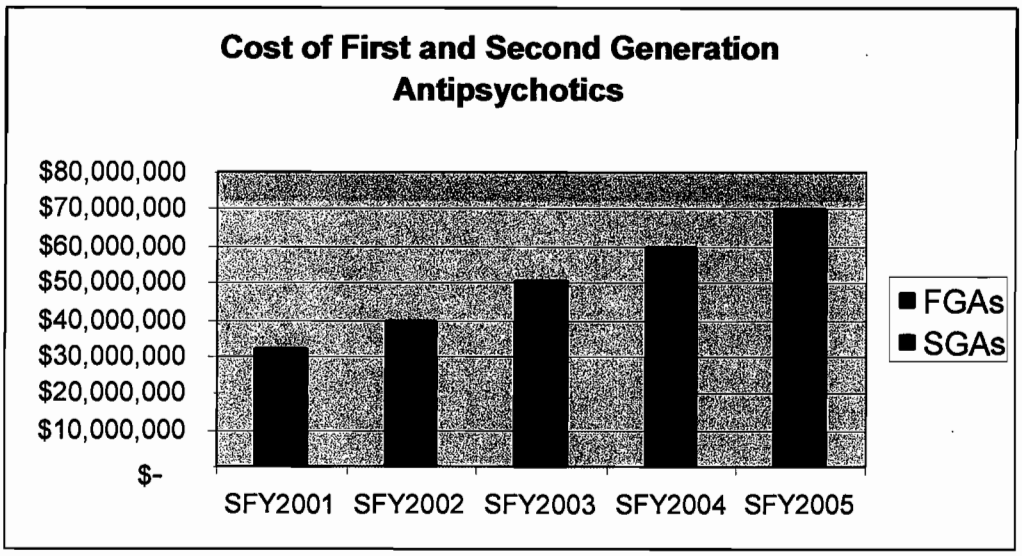


Figure 3: Costs of first and second generation antipsychotics for Iowa Medicaid

Part III - Process of the Subcommittee:

A total of six meetings were held, all via teleconference, each lasting approximately one hour, between September and December, 2005. A room was made available at the Iowa Medicaid Enterprise offices for people (non-subcommittee members) to listen to the discussion, but no public comment was elicited.

In general, it is fair to say that there was not a clear consensus among subcommittee members on the overall approach, and this did not change substantially throughout the course of the six discussions. Some members more consistently advocated for continued open access for all psychoactive medications. Other subcommittee members believe, due to the large and growing proportion that psychotropics represent compared to the overall Medicaid pharmacy budget, substantive steps should be taken to address this.

There was agreement however that these kinds of general policy decisions were not what was being asked of the subcommittee. Rather, the subcommittee was to review options that may lead to cost-saving while not compromising quality of care. These options would then be submitted, as potential strategies to the P&T committee, who would then review these in terms of clinical appropriateness and feasibility along with Iowa Medicaid Enterprise staff, and submit the resulting recommendations to the legislature for their consideration.

Concern was also raised about the appropriateness of making any substantive changes in the PDL policy during 2006 in light of the implementation of the Medicare Part D prescription drug plan. As "dual eligibles" (those eligible for both Medicaid and Medicare) account for a large proportion of the overall psychoactive medication budget, it will be very difficult to assess the effects of any changes in PDL policy when superimposed upon this potentially greater policy change. Therefore, changes in PDL policy may be more appropriate in the future, once baseline data post Medicare Part D implementation are available and understood.

That being said, what follows is a summary of the strategies that have emerged as possibilities for further consideration. The recommendations fall into three broad categories:

A) Strategies that would eliminate all or part of the current exemption of mental health drugs from the PDL process
B) Strategies that would require prior authorizations for specific clinical situations
C) Strategies that would largely maintain the current exemption, but perhaps lead to cost savings by targeting specific providers

The majority of the subcommittee agreed that while there was no clear consensus among the group and no clear way to achieve consensus as to which of these general approaches was most sound at this time, that difference of opinion and perspective favored the "middle ground" approaches detailed in category B.

Part IV – Potential Strategies Developed by the Subcommittee

Category A: Strategies that eliminate all or part of the MH exemption

A1. Eliminate exemption for MH drugs entirely
Under this plan, all classes of mental health drugs would undergo the same kind of process through the P&T committee that all non-exempt classes have already undergone. That is, an analysis would be done by the Iowa Medicaid Enterprise pharmacy team of the relative effectiveness and side effect profile of medications within a class. This would be presented to the P&T committee for recommendations. In those cases in which there did not appear to be clinically meaningful differences in effectives or side effects, financial factors would determine which drugs would be designated as preferred or non-preferred. All drugs would be available, but non-preferred would require prior authorization (PA).

Note - Under this plan, existing users would be "grandfathered." That is, if mental health drugs were no longer exempt from the PDL process, it would only affect new users and not existing users of specific mental health drugs.

A2. Eliminate exemption for specific classes of MH drugs
Under this plan, specific classes of MH medications would be subject to the traditional PDL process, but not necessarily all classes. The P&T committee would recommend specific classes be no longer protected by the exemption language in 249A.20A. For example, it could be limited to those classes that account for the largest costs, e.g., SGAs, and perhaps others including serotonin and noradrenalin reuptake inhibitors (SNRIs), or non-benzodiazepine hypnotics.

Again, under this plan, existing users would be grandfathered.

A3. Eliminate exemption for specific medications.

Under this plan, one or more specific drugs would be excluded from the exemption. This would target those individual medications that account for extremely high costs, e.g.,

- olanzapine – prior authorization with stepped approach required e.g., adequate trial(s) of other SGAs

Category B: Strategies that require prior authorization for specific clinical situations:

B1. Require Prior Authorization (PA) for one or more of the following clinical situations involving prolonged concomitant use of multiple medications within a class:

- (B1a) Multiple concomitant SGAs, used for more than a designated crossover-titration period (e.g., 12 weeks)

- (B1b) Multiple concomitant anticonvulsants (beyond crossover period)
- (B1c) Multiple concomitant antidepressants (excluding trazodone or tricyclic antidepressants (TCAs)) beyond crossover

B2. Require PA for prolonged use of specific medications outside of evidence-based therapeutic ranges as below:

- (B2a) quetiapine < 200mg/day (this would apply only to adults between ages 18 – 65)
- (B2b) risperidone > 8mg/day
- (B2c) olanzapine > 30mg/day

B3. Require PA for prolonged concomitant use of drugs within 3 or more of the following general classes:

- (B3a) Second generation antipsychotics
- (B3b) Anticonvulsants
- (B3c) Antidepressants other than TCA's, trazodone or generic fluoxetine

B4. Require PA for "off-label" use of the following in adults (ages 18 – 65):

- Second generation antipsychotics

Note – this would require a way to track diagnostic codes with each pres cription.

Category C: Strategies that largely maintain the current exemptions but may lead to cost savings by targeting specific practitioners

C1. Institute any or all of the changes above, but exempt psychiatric specialty providers from any of the PA restrictions.

Note – this would require that 1) the database used by the PA staff be able to identify practitioners by specialty and 2) a method was developed to determine who, other than psychiatrists, may be included as a psychiatric specialty provider

C2. More aggressively target "outliers", e.g., prescribers whose medication costs/patient are significantly outside the range of their peers, and institute one or more of the measures above for these providers.

This is a method that has been used with mixed results elsewhere. Details of how such an approach was used in Pennsylvania and Missouri are described in Appendix I. pages 2-4.

Finally, although the following option would not yield savings relative to psychoactive drugs at this time, it is one felt most appropriate by some subcommittee members at this time.

D. Maintain the MH exemption as it currently exists, with no changes for at least one year, and revisit the situation after the effects of Medicare Part D are better understood, and/or the effects of other federal legislation (e.g., appendix 2) are put in place.

Part V – Recommendations of the Full P & T Committee to the Legislature

All of the information above was carefully reviewed and discussed at length by the full P&T committee at their quarterly meeting on December 9th, 2005. On the previous day, three of the 27 public comments heard were on behalf of mental health advocacy groups, each making the case for continued unrestricted access for mental health drugs. The discussion on December 9th, 2005, included a closed session of the committee in which recent cost and utilization data for mental health medications in Iowa's Medicaid system over were reviewed.

The P&T committee discussed each of the options developed by the subcommittee in terms of their: 1) likelihood to negatively impact quality of care for Iowans with mental illnesses; 2) estimates of potential cost savings; and 3) feasibility of implementation.

After a prolonged discussion, in which all committee members indicated that they felt they had adequate information on which to base decisions regarding recommendations to the legislature, a motion to forward the following recommendations to the legislature was made and passed. (Seven members approved the motion, one member opposed, and one member was absent.)

The resulting recommendations are as follows:

1) Eliminate the PDL exemption for the SGA class of drugs. (Subcommittee recommendation A2).

Although there was reluctance on the part of several committee members to move in this direction, the majority of the committee was convinced that given the very high cost of these drugs, their rapidly increasing utilization, and the lack of evidence of benefit of one versus another, such a definitive step would ultimately be necessary. If it was not done this year, then it would probably have to be done some time soon. The committee was not convinced that the introduction of Medicare Part D in January 2006 should necessarily delay the implementation of this recommendation, and there were some advantages in making the change sooner rather than later. Specifically, Iowa's decision to do so at this time may affect policies in some of the other states with whom Iowa is collaborating for rebate negotiations.

Doing so would allow Iowa Medicaid Enterprise and its representatives to negotiate with the pharmaceutical industry in terms of providing meaningful rebates for the class of drugs that is accounting for the greatest proportion of mental health drug expenses. The SGA class would then be included in the preferred drug list (as opposed to the recommended drug list), and each medication in that class would be listed as either preferred or non-preferred. The categorization of preferred or non-preferred would by made by the P&T committee, in the same way these decisions are made for all other drugs on the PDL. Non-preferred drugs would require a prior authorization. This would be directed only at new starters, i.e., people for whom a clinical decision had been made to begin treatment with a SGA, who were not currently taking one. Current users would

be allowed to continue with whatever medication they were on, indefinitely, without a prior authorization (i.e., they would be "grandfathered in").

2) Develop and implement prior authorization protocols for prolonged concomitant use of multiple drugs within the same class (as detailed in subcommittee recommendations B1a-c).

The committee concluded that doing so would potentially improve the overall quality of care, and may result in significant cost-savings as well. This would not affect the status of a particular medication in terms of it being preferred, non-preferred, recommended or non-recommended. Rather, it would identify individuals who were being treated with multiple drugs within a class and require prior authorization to approve ongoing treatment, based on the clinical situation. The committee recognizes that there is little to no evidence supporting the effectiveness of concomitant use of medications within these classes, and indeed some evidence suggesting that such practices, although increasingly common, may have negative consequences (i.e., the side effects accumulate, while the efficacy does not).

3) Develop and implement prior authorization protocols for use of SGA medications outside of evidence-based dose ranges (as detailed in subcommittee recommendations B2a-c).

The committee was swayed by the recognition that a lot of the prescribing of some of the newer SGAs appears to be in doses inconsistent with the evidence base of their effectiveness. Much of this may be accounted for by the use of low doses of the more sedating medicines as a sleep aid. There are better and more cost-effective sleep aids, and such a prior authorization may curtail this type of inappropriate utilization without negatively impacting quality of care.

4) Implement a program to more aggressively target outliers (subcommittee recommendation C2).

This approach is has been used with mixed results in some states, but successfully in others (e.g., Missouri and Pennsylvania) as described in appendix 1, pages 2-4. The idea here is that providers whose prescribing patterns are consistently out of line with their peers, and with the existing evidence-base, would be identified and subject to a series of interventions, potentially including provider-specific prior authorization requirements. In terms of feasibility, this approach is the most complicated, and would require some investment of resources. Whether or not the state chose to pursue this strategy, the committee did think that it was important for the state to enhance their capacity to identify providers by specialty type.

The P & T committee did not support the other specific recommendations generated by the subcommittee at this time.

List of Appendices

Appendix 1: "Psychotropic Medications: Addressing Costs without Restricting Access"

This is one of a series of technical assistance papers developed in partnership with the Substance Abuse and Mental Health Services Agency (SAMHSA) to respond to the recommendations in the 2003 report issued by the President's New Freedom Commission on Mental Health.

Appendix 2: Summary of amendment proposed by Rep. Buyer (Indiana) contained in Section 3105 of the Budget Reconciliation Act, HR 4241

This amendment, currently being considered at the federal level, if passed, could prohibit state Medicaid agencies from restricting access to certain kinds of mental health medications, and would directly impact the initial recommendation of this report.

Appendix 1: "Psychotropic Medications: Addressing Costs without Restricting Access"

The current economic downturn has brought with it falling State revenues and increases in Medicaid enrollments. Coupled with increasing costs for prescription pharmaceuticals, this has induced State actions to contain Medicaid drug costs. This paper describes the current budget shortfalls in the States especially with regard to medication costs, the efficacy and costs of newer psychotropic medications, and innovative medication practices adopted by States in response to budget shortfalls. These practices represent efforts to address medication cost and quality of care issues within Medicaid without restricting access to specific medications.

I. Budget Shortfalls and Medication Costs

During the 1990s, the Medicaid program benefited from the nation's economic prosperity. After a decade of growth, however, the Federal and State governments are now dealing with an economic downturn and States are facing falling revenues. In this fiscal environment, States are examining ways in which Medicaid spending increases can be reduced.

For FY 2002, States reported the costs of prescription drugs as the most significant factor contributing to higher total Medicaid spending. States reported that increasing pharmacy costs resulted from increased utilization, new and more expensive medications, price inflation for existing products, and pharmacy driven capitation rate increases for managed care organizations.[1]

Because medications in general and psychotropic medications in particular were driving up Medicaid spending, a total of 24 States reported in 2002 that they had or planned in FY 2003 to take action to reduce the costs of prescription drugs.[2] To manage the demand for and cost of prescription drugs, States have used a variety of techniques, including mandating the use of generics, limiting the number of prescriptions that may be filled in a single month, imposing beneficiary co-payments, requiring prior authorization, and using fail-first policies (see Glossary).

II. Efficacy and Costs of Newer Psychotropic Medications

The recent development of new psychotropic medications has resulted in changes in the patterns of prescribing for individuals with mental illness. In the 1980s, selective serotonin reuptake inhibitors (SSRIs) such as Fluoxetine (Prozac) and Paroxetine (Paxil) replaced tricyclic medications such as amitriptyline and imipramine for depression.[3] More recently, a new generation of antipsychotic medications has come to the fore in the treatment of schizophrenia and other psychoses. These medications, including risperidone and olanzapine, are replacing the more traditional agents.[4] From a therapeutic perspective, these developments have been welcomed because studies have demonstrated that the medications are at least as effective as the older ones.[5] In addition, it has been postulated that the reduction in side effects associated with these drugs would result in increased compliance with medications and improved outcomes.[6]

However, while the new medications are more efficacious (i.e., they reduce symptoms and have fewer side effects), they also are much more costly. As a result, third party payers have closely scrutinized the unit cost of these newer medications. Cost and demand management techniques, such as prior authorization and targeted utilization review, are often implemented first. However, they can limit access to the most effective treatment for a specific individual, and have a negative effect on quality. Therefore, it is important to consider innovative alternatives that have the potential to both contain costs and improve the quality of care and outcomes.

III. Innovative Approaches

In 2001, the National Association of State Medicaid Directors (NASMD) and the National Association of State Mental Health Directors (NASMHPD) met and produced a joint report on psychiatric medications.[7] The report concluded that restrictive measures alone were unsuccessful, and pointed to the need to manage costs in the context of appropriate usage. It also recommended that agencies develop programs to improve provider compliance with medication use guidelines, and identify educational mechanisms for providers and consumers regarding appropriate medication use.

This section describes three innovative programs – a new educational intervention and outlier management program designed to align physician prescribing practices with best practice guidelines for prescribing, treatment algorithms developed for three major psychiatric disorders, and a program to identify and reduce polypharmacy.

A. The Pennsylvania and Missouri Approach

A large Medicaid HMO in Pennsylvania elected to introduce an educational behavioral pharmacy and outlier management program for prescribers into its management systems. The intervention is built on two premises supported by data: (1) the most significant driver of growth in Medicaid expenditures is related to the volume of drugs that are prescribed; and (2) the most significant behavior problem to be addressed is the inappropriate use of medications. The intervention targets deviations from best practices, as well as cost-insensitive prescribing. It is designed to be an alternative to restrictive formularies and prior authorizations, which increase the risk of use of multiple prescriptions, reduced compliance, and poor outcomes.

This program identifies areas of concern and executes targeted expert interventions with the aim of influencing physician prescribing behavior. The targeted educational system provides direct interventions to assist high-volume physicians in obtaining the most current information on evidence-based practices.

The Behavioral Prescriber and Outlier Management System used as part of this intervention includes three intervention levels, and materials are continuously monitored and updated to improve quality and educational content.[8] A basic prescription data set is used for analysis.

To provide clinically and economically meaningful data analysis, the Pharmacy Management System currently uses a health plan or State's monthly paid pharmacy claims file. The process compares 95 central nervous system medications (antipsychotics, antidepressants, sedative hypnotics and anticonvulsants) with 12 best practice prescribing behaviors. A physician prescribing profile is thus developed. Examples of best practice comparisons include therapeutic duplications of atypical antipsychotics, cost-ineffective pill strength selection, use of two or more drugs from the same chemical class, and evidence of excessive switching of antipsychotics. This analysis tool has also produced data identifying some outlier trends in prescribing practices related to "switching", which involves changing prescriptions from one anti-psychotic drug to another within a short timeframe. Another outlier trend is the increasing use of heavy dosages of sedatives for persons also taking atypical medications. The ability to identify emerging trends and apply educational interventions to drive prescribing practice patterns toward best practices is the major feature of this intervention.

Physician interventions are designed to be progressive in nature (there are three levels of progression), depending on size of caseload and prescribing behaviors. Level I interventions begin with prescribing practice outlier physicians receiving quality letters monthly with documentation of evidence to support best practice. The letters designed for this specific health plan are co-signed by the county health commissioner and the medical director of the health plan. These high volume outlier physicians also receive patient profile data. The letters present best practice information including an annotated bibliography, an article from a peer-reviewed journal, the Expert Consensus Guideline Series on behavioral health when applicable, and other best practice literature. Monthly reporting and on-going analysis are core features of this intervention.

Level II interventions are targeted for specific behavioral health prescribers based on the data analyses and prescribing patterns that emerge over time. These interventions include the use of Awareness/Fact sheets. Targeted prescribers receive a detailed claims data report and are requested to address the accuracy of the data and to address discontinuation/compliance issues with specified patients. A second intervention used at this level is a letter that provides detailed claims data, sorted by patient and by prescriber. The letter references clinical information relevant to a specific data issue. A final level II intervention is a benchmarking report that ranks physicians and patients against each other for type, frequency, and cost by each drug class utilized. This type of normative report has been effective in producing change in the desired direction as "outliers" make adjustments in their prescribing patterns to weigh in more toward the mean and in line with the "average" practice.

Level III interventions are customized to a specific prescriber or to a group of prescribers around a specific clinical issue. Interventions may include a targeted medical education program, peer review by the medical director for this project, or a pharmacy review of data meeting high use/high deviation criteria. All interventions are educational and consultative.

These interventions are based on the assumptions that altering physician-prescribing behaviors is critical if the desired changes are to be achieved and that the quality of

prescribing practice can be significantly improved through improved education and the use of best practice treatment guidelines as opposed to more traditional control methods such as restricting formularies or prior authorization of drugs. Physicians demonstrate marked variation in their comfort level with making the recommended changes. Responses occur on a continuum from defensiveness about their practices based on real hesitations about using guidelines to acknowledgement that there is room for improvement in their prescribing practices. Others will be aware of the issues raised and be willing to accept resources to foster improvement while another segment will pursue educational opportunities and adjust their prescribing behaviors.

On the patient side, patients with evidence of high utilization of multiple antipsychotics, extended utilization of the same, complicated or "risky" combination of medications, evidence of multiple prescribers, and repeated evidence of discontinuation may be referred for augmented case management.

Key quality and cost findings at the end of the first year of operations for the health plan include:

- Reduction in polypharmacy and associated medical risk to members,
- Reduction in multiple prescribers,
- Reduction in therapeutic duplication of atypical antipsychotics, and
- Reduction in per member/per month costs from growth trend, despite a rise in the proportion of "disabled" members in the case mix.

Missouri is the first state to adopt the BPMS for statewide Medicaid behavioral health prescribers. In March 2003, Missouri established the Missouri Mental Health Medicaid Pharmacy Partnership. The goal of the partnership is to improve the clinical quality of psychotropic medication therapies. The Missouri approach differs in its initial implementation from Pennsylvania in that Missouri has formed an Advisory Council to:

- Assist in selecting the best opportunities for improving prescribing practices,
- Assist in making the communications to physicians helpful in content and supportive in tone, and
- Assure that best practice recommendations are current and appropriate.

The Advisory Council includes broad representation from the practice community. Among its members are three representatives from in-state psychiatric societies, four medical school psychiatry clinics, a representative from the Community Mental Health Coalition and Group Practices, advocacy organizations, and from Medicaid and the Department of Mental Health. Psychiatrists are heavily represented on this advisory council. The intent is to obtain buy-in to the project, its goals, findings, and recommendations from the groups representing psychiatrists across the state. This newly launched project is using an inclusionary strategy in its effort to improve physician prescribing practices.

For further information on this intervention you may contact Dr. Sandra Forquer at sforquer@cnsmail.com or by telephone on 719-538-9922.

B. The Texas Approach

The Texas Medication Algorithm Project (TMAP) is a collaborative effort that has led to the development of evidence-based treatment guidelines for three major psychiatric disorders – schizophrenia, major depressive disorder, and bipolar disorder. TMAP began in 1996 and involves a consortium (government and academic) including the Texas Department of Mental Health and Mental Retardation (MHMR). TMAP was designed to "develop, implement, and evaluate an algorithm-driven treatment philosophy for major adult psychiatric disorders treated in the Texas public mental health sector."[9] The target population for TMAP is persons with serious and chronic mental illness who are served by public programs.

The goals of TMAP are twofold: 1) to improve the quality of care and achieve the best possible patient outcomes for the resources expended; and 2) to develop and continuously update treatment algorithms and use them to reduce the immediate and long-term emotional, physical and financial burdens of mental disorders for clients, their families, and their health care systems.[10] The components of TMAP include:

1) Evidence-based, consensually agreed upon medication treatment algorithms,
2) Clinical and technical support necessary to allow clinicians to implement the algorithms,
3) Patient and family education programs (which describe the nature of the illness and the effects of various medications) that allow the patient to be an active partner in care, and
4) Uniform documentation of care provided and resulting patient outcomes.

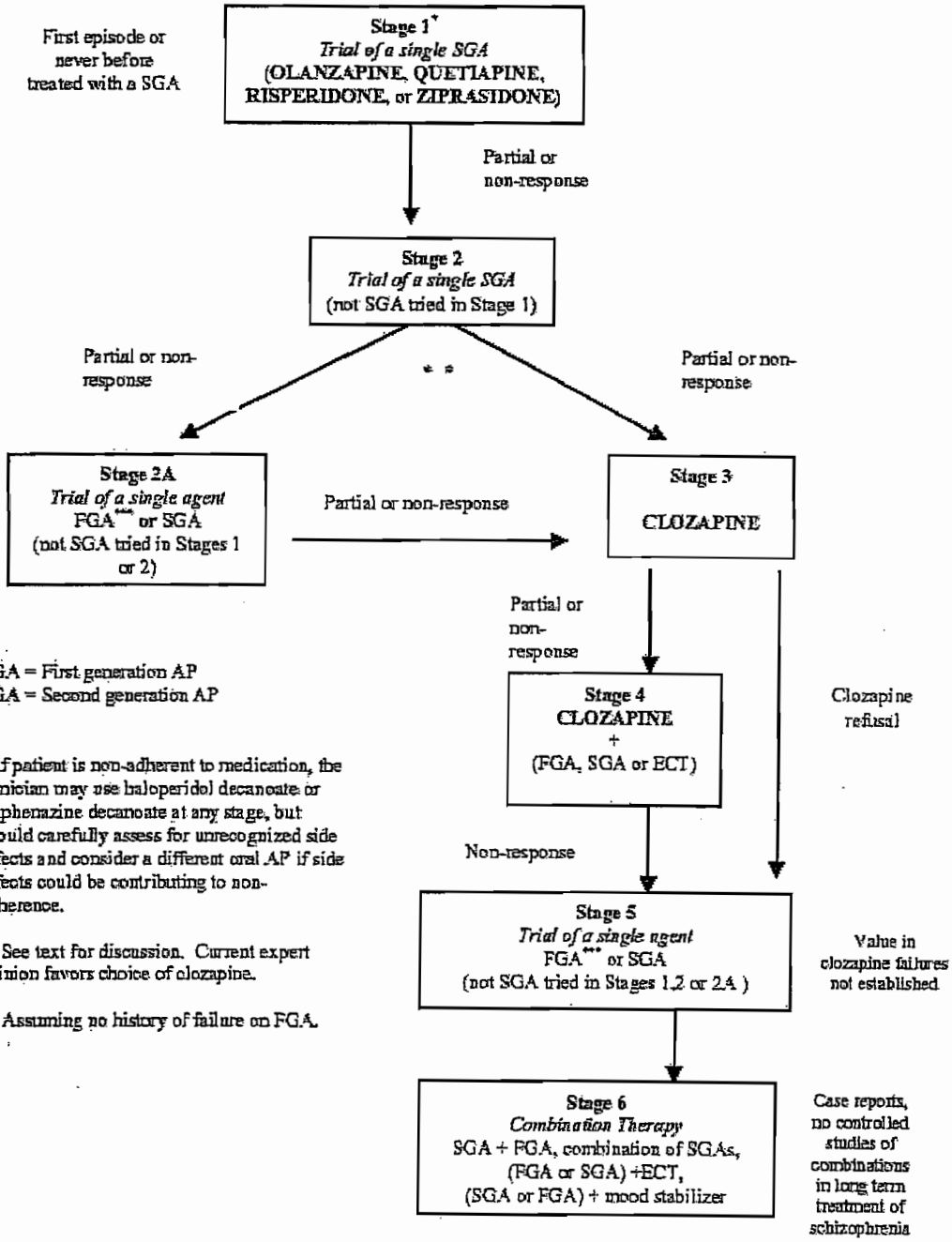
In addition, TMAP involves 1) a prospective comparison of the clinical outcomes and economic costs of using these medication guidelines with "treatment as usual" within the Texas MHMR system, and 2) implementation of these algorithms in the "real world" of the clinics and hospitals of the Texas Department of MHMR.[11]

The TMAP model uses algorithms (or step-by-step procedures) in the form of flow charts to help physicians deliver quality care based on making the best choice of medications and an assessment of their effectiveness. While algorithms do not dictate clinical answers, they provide a framework that clinicians use and which should yield similar treatment approaches in similar clinical situations.[12] The algorithms provide guidance regarding treatment regimens, including issues such as choice of "initial medication(s), initial dosage, dosage changes, methods to assess response to treatment, frequency of assessment and re-evaluation, and minimum and maximum treatment periods in order to assess adequacy of therapeutic response."[13] The algorithms were developed by systematically obtaining input from groups of clinicians, consultants, and consumers. Each algorithm was initially tested in five sites within the Texas public mental health system. The algorithm package consists of multiple components – patient education, frequent medical visits, medication availability, and consultation. The algorithm basically provides a framework for clinical decision making, with multiple options given (if possible) at each stage so that the patient's treatment plan can be altered to obtain optimal outcomes. There are a series of treatment steps that are determined by the patient's clinical response to the preceding step.

As an example, for schizophrenia, there are six stages of treatment in the current version of the algorithm (see Figure on next page and details in the TIMA schizophrenia physician's manual at http://www.mhmr.state.tx.us/centraloffice/medicaldirector/ timasczman.pdf).[14] For patients experiencing their first episode of schizophrenia or who have never before been treated with a second generation anti-psychotic (e.g., olanzapine, quetiapine, risperidone, or ziprasidone), the first stage involves use of one of four different types of these second-generation anti-psychotic medications. If the patient responds favorably to the medication, the drug is continued and moved into a maintenance phase where indicated. If the patient does not respond favorably to the drug given at stage 1, he or she moves to stage 2, where a different one of the four types of anti-psychotic medications (from stage 1) is given. Stage 2a involves trial of a single first generation or second generation (other than the ones tried in Stages 1 and 2) anti-psychotic. In stage 3, clozapine is used. Stage 4 involves the use of clozapine and a first generation or second generation anti-psychotic or electroconvulsive therapy (ECT). The final stage involves combination therapy – a first generation anti-psychotic and a second generation anti-psychotic, or a combination of second generation anti-psychotics, or a first generation or second generation anti-psychotic plus ECT, or a first generation or second generation anti-psychotic plus a mood stabilizer.

Choice of antipsychotic (AP) should be guided by considering the clinical characteristics of the patient and the efficacy and side effect profiles of the medication

Any stage(s) can be skipped depending on the clinical picture or history of antipsychotic failures



FGA = First generation AP
SGA = Second generation AP

* If patient is non-adherent to medication, the clinician may use haloperidol decanoate or fluphenazine decanoate at any stage, but should carefully assess for unrecognized side effects and consider a different oral AP if side effects could be contributing to non-adherence.

** See text for discussion. Current expert opinion favors choice of clozapine.

*** Assuming no history of failure on FGA.

In terms of providing clinicians with information to help guide their decisions about which medication to use, the appropriate dose, and the duration of treatment, the TIMA Schizophrenia Physician's Manual includes information to guide decision making at critical decision points (CDPs), which are "the point in the course of the medication trial when the clinician decides whether to continue the present medication regimen, adjust the medication dose, or move on to another medication." At each CDP, clinicians evaluate the patient's level of response to the antipsychotic. As an example, for schizophrenia, clinicians initially choose between one of the second-generation antipsychotics, a therapeutic dose of the drug is determined during the first week, and then the patient is seen for each of the next four weeks to evaluate drug tolerability and the need for dosage adjustments, as well as to monitor for symptom improvement or deterioration, side effects, etc. The clinician then determines if the patient has improved adequately (i.e., an improvement in symptoms), such that the dosage can be maintained; otherwise, adjustments to dosage or movement to the next stage of the algorithm are recommended. Subsequent CDPs occur at 8 and 12 weeks. If a patient has not achieved positive symptom reduction goals as specified in the user's manual by 12 weeks, it is recommended that treatment move to the next stage of the algorithm. Separate CDPs are specified for the use of clozapine. The Physician's Manual also includes information on average doses for each drug, with recommended adjustments (e.g., average daily dose of risperidone is 4-5 mg/day, which is adjusted in 1-2 mg increments every 3-7 days).

One of the main areas of focus in the TMAP program is to ensure that people with any of the three disorders are receiving the clinically appropriate and most effective medications for their disorders. TMAP tries to provide ongoing information about the research on medications, as well as how to measure their effectiveness. Key recommendations include:

- Multiple same therapeutic-class medications should only be a last resort, and
- When working to find an appropriate medication, make sure that the person receives an appropriate dose and tests the medication for an adequate time period.[15]

Evaluations of TMAP have shown that it is more effective than standard treatment for the three major psychiatric disorders addressed by the treatment algorithms.[16] Positive clinical outcomes include 1) a faster response to treatment than for persons not in the program, 2) a greater improvement in cognition, and 3) positive clinical outcomes being maintained more effectively over time.

There are specific outcomes measures for the each of the three diagnoses. For schizophrenia, TMAP has resulted in a higher level of cognitive functioning and a more rapid reduction in the positive symptoms of the disorder.[17] Cognitive functioning is viewed as a critical feature in reducing both positive symptoms (e.g., suspiciousness, unusual thought content, hallucinations) and negative symptoms (e.g., prolonged time to respond, reduced social drive, poor grooming and hygiene) of the disorder.[18]

For bipolar disorder, manic symptoms for individuals in TMAP decreased more significantly than for those not in TMAP, and the difference in symptoms was maintained over time.[19] For individuals with major depression, both groups improved with treatment, but individuals in TMAP had a markedly better response, which was maintained over time.[20]

The TMAP team is analyzing the effects on service use and health care costs with results to be submitted for publication during 2004. Based on its success in Texas, the TMAP approach has been adopted to varying degrees by health organizations in 11 other states plus the District of Columbia.[21]

TMAP has also developed medication algorithms for two common children's mental disorders: attention deficit hyperactivity disorder (ADHD)[22] and childhood depression. Successful feasibility testing has been completed with both of these, and the algorithms are currently under revision. Implementation of these algorithms in the Texas public mental health system will occur during 2005. Algorithms for the treatment of substance use disorders co-occurring with major depression, bipolar disorder, and schizophrenia are in the final stages of development.

From TMAP's experience to date, there are several key components of the program: 1) all medications in the algorithm must be available in the formulary and all formulary decisions must be based on overall effectiveness of treatment, not just drug cost; 2) it is vital to allow enough time for medications to work and consumer visits with clinicians should be as frequent as clinically necessary; 3) consumers and families must be educated and work in partnership with physicians to choose the medications used; and 4) when clinicians reach a decision point on the algorithm, such as whether to change medication or increase dosage, the best guide to making that decision is to rate the patient's actual symptoms.

C. The Massachusetts Approach

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 pharmacologic action to treat different conditions."[23] There are both cost and quality of care issues related to the use of multiple prescription drugs, particularly multiple drugs within the same therapeutic class. Quality of care can be compromised by potential drug interactions, both through increased side effects and decreased efficacy of one or more drugs.[24] Further, multiple prescriptions within the same therapeutic class rarely represent best practices.

The state of Massachusetts has a clinical work group to address polypharmacy, including psychopharmachologists, members of the Massachusetts Psychiatric Society, and representatives of the Department of Mental Health, the Division of Medical Assistance, the state Pharmacy Program, and the Alliance for the Mentally Ill. The workgroup's analysis of Massachusetts Medicaid drug data showed that "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."[25] In response to these findings, the Massachusetts Medicaid program has begun to educate prescribers about the costs of various prescribing patterns as well as the threat escalating prescription drug costs pose to enrollee access to these drugs. While acknowledging that polypharmacy is essential for some patients, the Medicaid program

also has identified the physicians who are outliers (i.e., those who routinely use polypharmacy approaches) and will work to educate them about their "prescribing practices and the evidence base as it relates to the type of patients they treat."[26]

While the overall costs associated with polypharmacy are unknown, one pharmacy benefits manager, Prescription Solutions, reported that unneeded prescriptions can cost up to $50 billion annually. An estimate of savings in psychiatric drug costs for the state of Massachusetts, by implementing the program described above, is $10 million. This projected savings represents about 2% of the state's current spending on psychiatric drugs.[27]

Glossary

Dispensing or Prescribing Limits - Restrictions on the number of prescriptions per month, or the amount of medication that may be prescribed in a given time frame (e.g., a 90-day limit at each pharmacy).

Drug Formulary - A list of medications that consumers may readily access through their health plans. Non-formulary medications may not be accessible or may be accessible only if prior authorization is obtained.

Drug Utilization Review (DUR) - Efforts to control drug utilization and costs by a facility or a health plan. Common methods include the use of a formulary (see above), substitution of generic products for more expensive name brands and encouraging use of drugs that will trigger rebates or discounts.

Fail-First Policies – Requirement that as a prerequisite for authorization of a specific, often non-formulary medication, the patient fail on at least one other medication (often involves multiple tries).

Generic Substitution – The practice of substituting a cheaper, generic medication for a brand-name medication. This can be mandated by the state to occur at the point of sale or can occur at consumer request.

Pharmacy and Therapeutics Committee (P&T Committee) – A committee, usually made up of physicians, pharmacists, and other medical staff, that develops the list of medications that are on the prescription drug formulary and/or require prior approval.

Pharmaceutical Benefits Manager (PBM) - An entity that is responsible for managing prescription benefits.

Prior Authorization/Approval - A cost-control procedure in which a payer requires a service to be approved for coverage in advance of delivery.

Reference-based formulary – Identifies categories of drugs that are similar in effectiveness, but with a range of cost. The most cost-effective drug would become the reference drug and set the maximum price paid by the State for that category.

Therapeutic Class Substitution – A different medication from the same therapeutic class is substituted. Often a formulary will list one or two medications from each therapeutic class, rather than allowing access to a full array of medications.

Tiered Co-payment Structure – Different co-payments are set for brand and generic medications.

References

[1] "Medicaid and Prescription Drugs," Kaiser Commission on Medicaid and the Uninsured, October 2002.

[2] Smith, V., Gifford, K., Ramesh, R., Wachino, V., "Medicaid Spending Growth: A 50-State Update for Fiscal year 2003," Kaiser Commission on Medicaid and the Uninsured, January 2003, 1-21.

[3] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health, Mental Health: A Report of the Surgeon General, 1999 .

[4] Worrel, J.A., "Atypical Antipsychotic Agents: A Critical Review", American Journal of Health Systems Pharmacy, 57, 238-258, 2000.

[5] Brown, C.S., "Atypical Anti-Psychotics: Part II, Adverse Effects, Drug Interactions and Costs," Annals of Pharmacotherapy, 33, 210-217, 1999.

[6] Ibid.

[7] Evidence and Action: The National Association of State Mental Health Program Directors/National Association of State Medicaid Directors Technical Report on Psychiatric Medications, NASMHPD Research Institute, Alexandria, Virginia: 2001.

[8] Comprehensive NeuroScience, Inc. White Plains, NY. Patent pending. 2002.

[9] http://www.mhmr.state.tx.us/centraloffice/medicaldirector/TMAPover.html

[10] Ibid.

[11] Ibid.

[12] TIMA Schizophrenia Physician's Manual, p. 6, January 8, 2003.

[13] Ibid.

[14] Two other widely reference treatment guidelines for schizophrenia are available at www.psychguides.com/gl-treatment_of_schizophrenia_1999.html and www.psych.org/clin_res/pg_schizo.cfm

[15] Many physicians and patients, in an effort to find an effective medication right away, do not wait long enough to determine if a medication is effective. Research is now finding that it often takes up to four months to see the full impact of certain antidepressants. TMAP is now recommending staying with one type of medication and treating symptoms with other medications for that test period.

[16] Personal communication with Steven Shon, March 2003.

[17] TIMA Schizophrenia Physician's Manual, p. 2, January 8, 2003.

[18] TMAP. NorthSTAR Implementation Planning Team Presentation (12-13-2002).

[19] Ibid.

[20] Ibid.

[21] "University of Texas at Austin Pharmacy professor's efforts in mental health system reform presented to President Bush," Jan 17 2003. http://www.utexas.edu/admin/opa/news/03newsreleases/nr_200301/nr_pharmacy030117.html

[22] Steven R. Pliszka, M.D.; Molly Lopez, Ph.D.; M. Lynn Crismon, Pharm.D.; Marcia G. Toprac, Ph.D.; Carroll W. Hughes, Ph.D.; Graham J. Emslie, M.D.; Christine Boemer, B.A. (2003). A Feasibility Study of the Children's Medication Algorithm Project (CMAP) Algorithm for the Treatment of ADHD. Journal of the American Academy of Child & Adolescent Psychiatry; 42(3):279-287.

[23] Kingsbury, SJ, Yi, D, and Simpson, GM. (2001). "Rational and Irrational Polypharmacy," Psychiatric Services, 52(8): 1033-1034, 1036.

[24] U.S. Department of Health and Human Services, Substance Abuse and Mental Health Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health, Mental Health: A Report of the Surgeon General, 1999 , Chapter 5.

[25] 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.

[26] Ibid.

[27] http://www.aishealth.com/drugcosts/dcmrstatespsych.html

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Appendix 2: Summary of Rep. Buyer amendment

The House Energy and Commerce Committee Medicaid Conciliation Report Documents (http://energycommerce.house.gov/108/11092005_medicaid/Medicaid%20Reconciliation%20Report.pdf) provide this summary:

"Section 3105. Improving patient outcomes through greater reliance on sc ience and best practices. Current Law. In general, Medicaid beneficiaries receiving care in the fee-for-service sector are assured of broad pharmaceutical coverage due to statutory requirements within the rebate agreements between states and the drug manufacturers. In return for entering into agreements with the Secretary, state Medicaid programs are required to cover all of the drugs marketed by those manufacturers (with possible exceptions for the categories of drugs that states are allowed to exclude from coverage). Currently, states do have a number of techniques to control cost and utilization of pharmaceuticals. One of those techniques is prior authorization. Prior authorization is the requirement that only pharmaceutical products for which advance approval is sought and received from a designated individual or entity are to be covered. States may establish prior authorization programs under Medicaid for all drugs or for certain classes of drugs, as long as these programs meet two criteria: (1) they must respond within 24 hours to a request for approval, and (2) they must dispense at least a 72-hour supply of a covered drug in emergency situations. In 2002, all (including the District of Columbia) but four states report having a prior authorization procedure for at least some covered drugs.

"Explanation of Provision. Section 3105 would require that an atypical antipsychotic (SGA) or antidepressant single source drug may be subject to prior authorization only when a drug use review board has determined, based on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data and other information as the board determines to be appropriate, that placing the drug on prior approval or otherwise imposing restrictions on its use is not likely to harm patients or increase overall medical costs. Additionally, if a response is not received for an atypical antipsychotic (SGA) or antidepressant drug prescribed within 24 hours after the prescription is transmitted, payment is made for a 30 day supply of the medication.
"Section 3105 would take effect January 1, 2007."