

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.

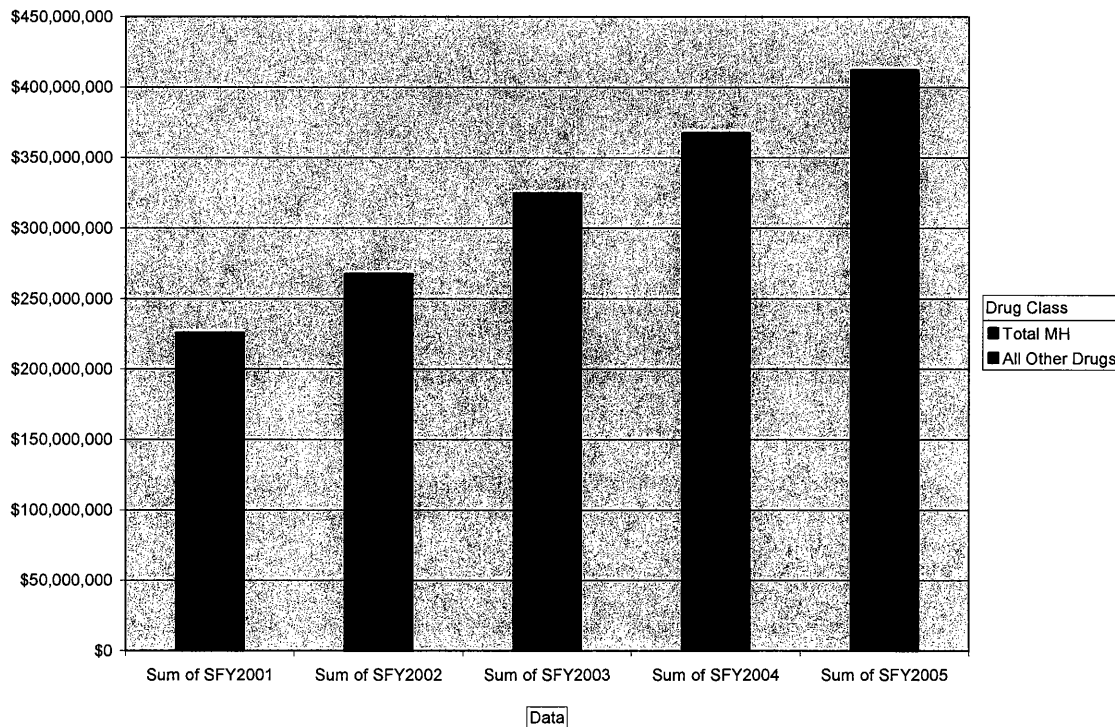


Figure 1: Total Drug Costs for Iowa Medicaid by Mental Health (MH) and All Other Classes

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 realized².

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.

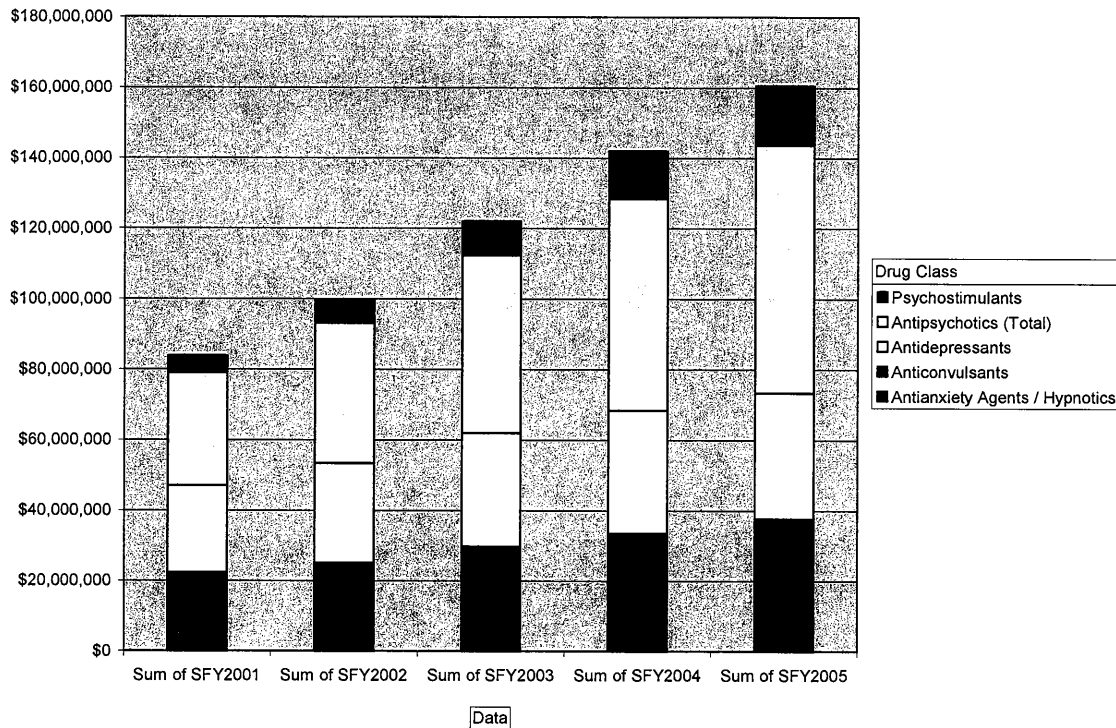


Figure 2: Costs by MH Drug Class

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.

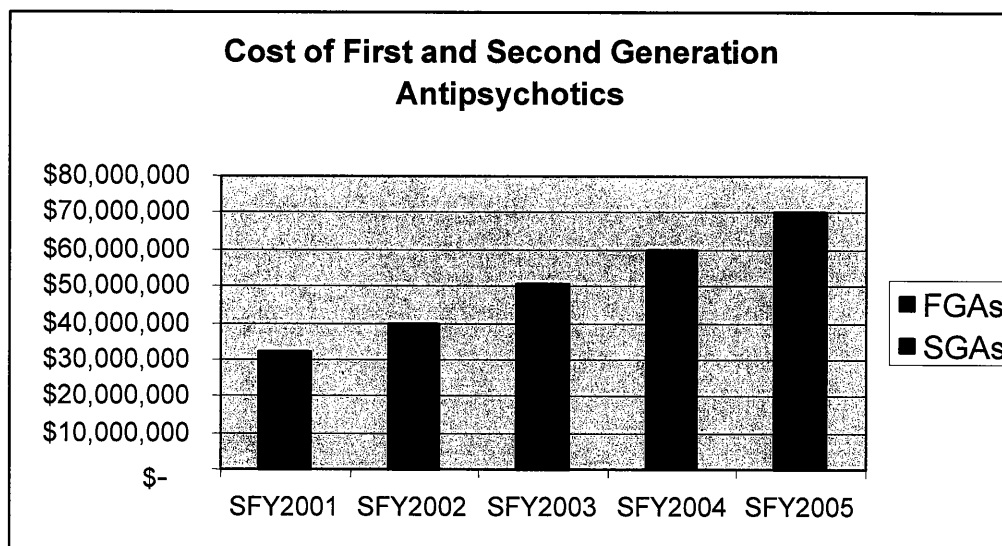


Figure 3: Costs of first and second generation antipsychotics for Iowa Medicaid

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 effectiveness 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 prescription.

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 be 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

