Medical Assistance Pharmaceutical and Therapeutics Committee Report to the Legislature:

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

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December, 2005

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 and T committee; 2) requests for representation from Iowa Medical Society, Iowa Psychiatric Society, the Iowa Association of Nurse Practitioner 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

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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 5 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.

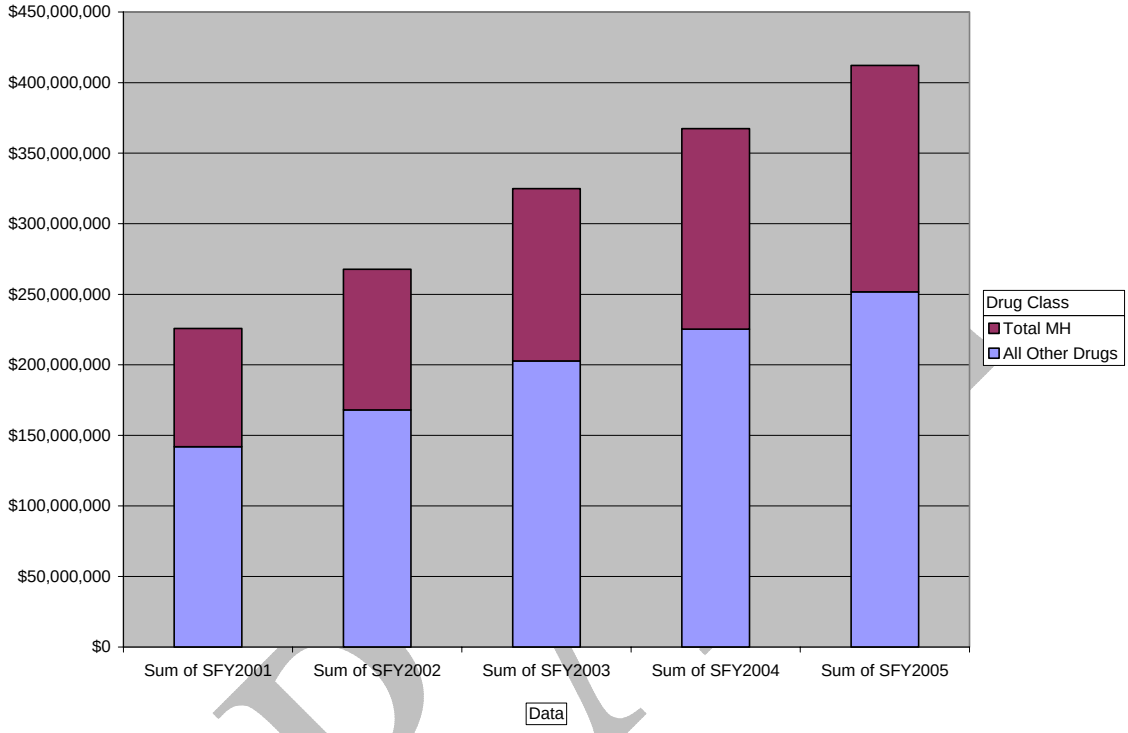

Figure 1: Total Drug Costs for Iowa Medicaid by Mental Health (MH) and All Other Classes

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 5 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.

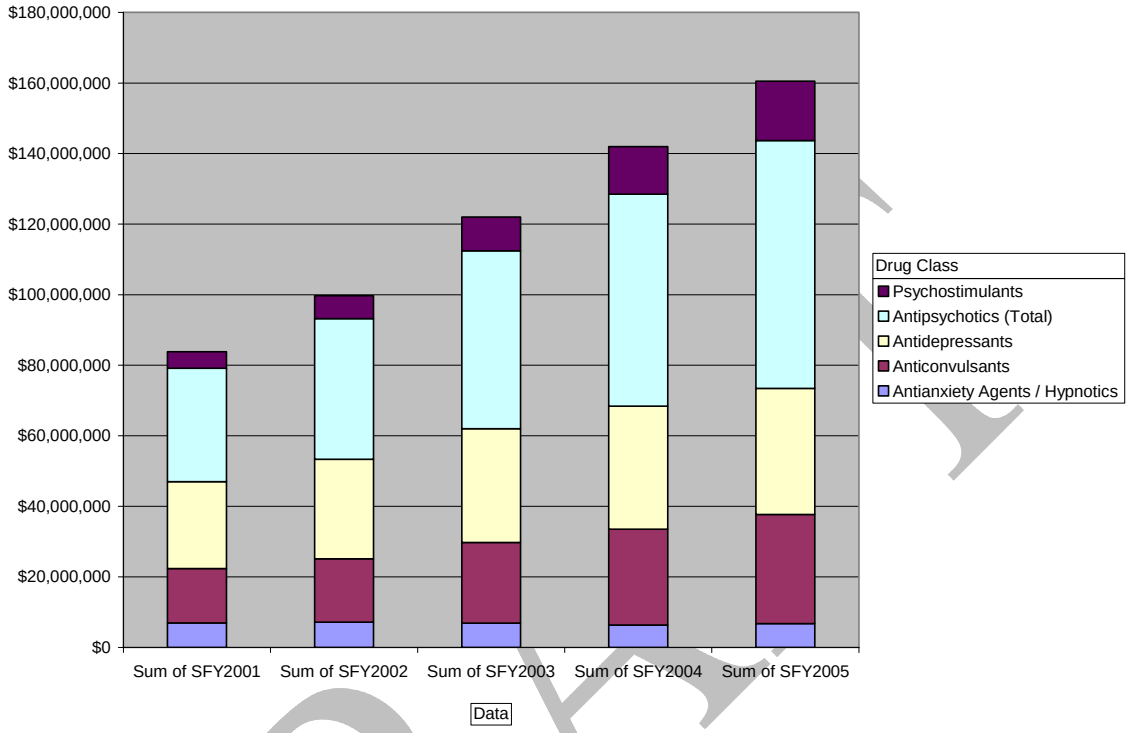

Figure 2: Costs by MH Drug Class

Introduction of "Atypical Antipsychotics": The biggest change has involved the introduction and widescale use "atypical" or "second generation" antipsychotics (SGA's)", distinguishing them from the "typical" antipsychotics that have been in wide use for the past half century. Clozapine / Clozaril®, FDA approved in the US in 1990 was the 1st SGA. While shown to be superior in efficacy to typicals, its side effect profile limited its widespread use. However, since the mid 1990's, 5 other SGA's 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 typicals. Each of the 5 other SGA's have at least equivalent efficacy to the FGA's, 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 FGA's is being reconsidered in light of other side effects of the SGA's (most notably higher rates of diabetes mellitus).

Costs: Each of the SGA's are quite expensive relative to the typicals. 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

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SFY'05 for Iowa Medicaid was $36. A month's supply of any of the SGA's 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 SGA's in SFY '05 for Iowa Medicaid was $230.

Increased utilization and indications for SGA's: In addition to the markedly increased cost of this class of medications relative to their predecessors, they are being prescribed much more often. Typical antipsychotics 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 SGA's 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 SGA's in acute mania of BPAD type I to all areas of bipolar disorder. There is also increasing evidence of effectiveness of SGA's 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 5 years.

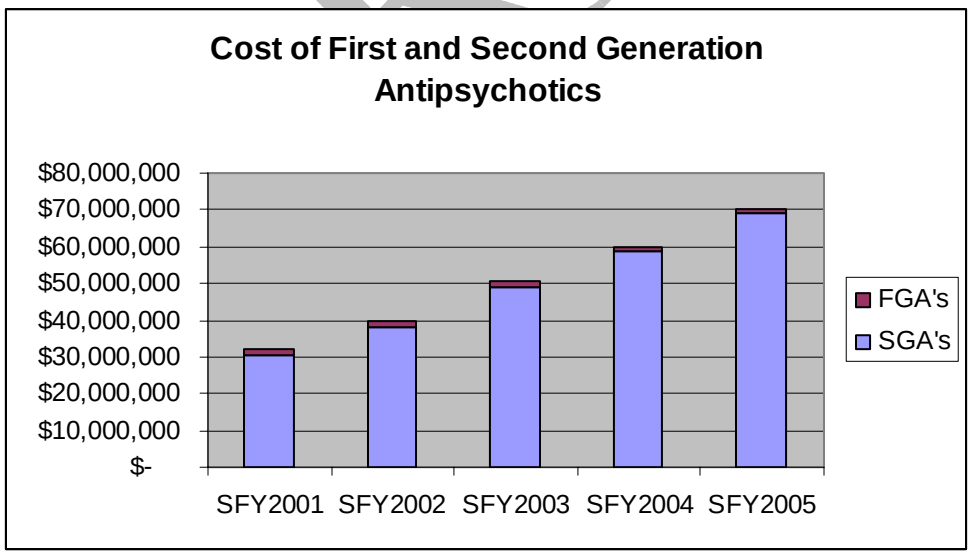

Figure 3: Costs of first and second Generation Antipsychotics for Iowa Medicaid

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Part III - Process of the Subcommittee: A total of 6 meetings were held, all via teleconference, each lasting approximately 1 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 6 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 and T committee, who would then review these in terms of clinical appropriateness and feasibility along with IME 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 3 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.

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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 Dr. Clifford's group, 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, 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., second generation antipsychotics (SGA's,), and perhaps others including serotonin and noradrenalin reuptake inhibitors (SNRI's), 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 – PA with stepped approach required e.g., adequate trial(s) of other SGA's

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 second generation antipsychotics (SGA's), used for more than a designated crossover-titration period (e.g., 12 weeks)
- (B1b) Multiple concomitant anticonvulsants (beyond crossover period)

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- (B1c) Multiple concomitant antidepressants (excluding trazodone or tricyclic antidepressants (TCA's)) 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 (between 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. pp 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.

- **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.**

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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, the committee heard numerous public comments from various mental health advocacy groups, all making the case for continued unrestricted access for mental health drugs. The discussion on Dec 9th 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.

The resulting recommendations are as follows:

1) Eliminate the PDL exemption for the "atypical antipsychotics" class of drugs. (Subcommittee recommendation 2A).

Doing so would allow IME 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 atypical antipsychotic 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 and 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 an atypical antipsychotic, 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").

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 in the "consortium". *(if we go with this – more explanation probably necessary -MF).*

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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 sum, while the efficacy does not).

3) Develop and implement prior authorization protocols for use of specific atypical antipsychotic 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 atypical antipsychotics appears to be in doses inconsistent with the evidence base of their effectiveness. Much of this may be accounted for by 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 other states, but successfully in some (e.g., Missouri and Pennsylvania) as described in appendix 1, pp 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.

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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

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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 science and best practices. Current Law. In general, Medicaid beneficiaries receiving care in the fee-forservice 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 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 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."

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