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**Estimate of the Net Cost of A Prior Authorization
Requirement for Certain Mental Health Medications**

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for

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Executive Summary

Background

The Ohio Department of Jobs and Family Services (ODJFS) has under consideration a requirement for prior authorization for the prescription of certain psychotropic drugs for patients with schizophrenia, bipolar disorder, and other serious forms of mental illness.

Alleged Savings

Originally, ODJFS claimed that a prior authorization policy would save \$47 million in Medicaid costs. After two revisions, ODJFS cannot quantify any potential savings from prior authorization policies.

Documented Costs

Much research has focused on the costs caused by the implementation of prior authorization requirements for drugs prescribed for the mentally ill in other states. Application of this research to Ohio enables the quantification of millions of dollars of additional costs as an unintended outcome of a prior authorization program for psychotropic drugs.

- 1) Based on estimates about the number of persons with schizophrenia and bipolar disorder in the Ohio Medicaid program suggest that 33,750 persons with such diagnoses would be affected by prior authorization requirements.
- 2) Research supports an estimate that prior authorization will increase the number of lapses in care for this population by 6%.
- 3) Other research shows that 80% of persons whose care lapses suffer expensive adverse consequences.
- 4) These adverse consequences include higher medical costs, hospitalization, lost wages, homelessness, and incarceration.
- 5) The table below summarizes prior authorization benefits and costs:

Category	Savings	Additional Cost
Savings in Medicaid Pharmacy Cost	Unknown	
Additional Administrative Cost (PA review)		Positive but Unclear
Additional Compliance Cost by Providers		Positive but Unclear
Medical costs of schizophrenic and bipolar patients		\$17,415,000- \$29,025,000
Medical costs of severely depressed patients		Not estimated
Medical costs of fee-for-service patients if supplemental rebate plan implemented		\$5,805,000 - \$9,675,000
Cost of lost wages of the severely mentally ill		\$16,000 per person
Annual emergency shelter cost per person		\$12,000 per person
Annual mental health services per inmate		\$10,000 per person
Average annual total per inmate cost in Ohio prisons		\$25,000 per person
Total	Unknown	\$23,220,000 - \$38,700,000

Estimate of the Net Cost of A Prior Authorization Requirement for Certain Mental Health Medications

Background

Ohio is currently considering the implementation of a “prior authorization” policy that would affect access to medications for mental health patients who receive care under the Medicaid programs. The principle objective of prior authorization is to control the pharmaceutical utilization of higher cost drugs. Typically, this is done by creating a preferred drug list (PDL) which includes lower cost drugs. Drugs from the PDL can be prescribed without authorization while those not on the list (the higher cost drugs) require approval. The objective is to save the state money in the Medicaid pharmacy budget by using lower cost drugs first. The insinuation is that doctors treating mental health patients are inappropriately prescribing higher cost drugs. The risk is that implementing a prior authorization policy for mental health patients in Ohio will compromise the quality of patient care and thereby end up costing the state money rather than saving it.

In May 2007, the Ohio Department of Jobs and Family Services (ODJFS) released an estimate showing an anticipated cost savings of \$47 million from prior authorization. In December 2007 this estimate was revised downward to \$20 million. Finally, in testimony before the House Finance and Appropriations Committee in December of 2007, OBM Director Pari Sabety distributed a document that showed the anticipated cost savings to be \$0. As related to any saving anticipated from the proposed supplemental rebate system for atypical antipsychotics and antidepressants (see page 5, item 8), ODJFS has acknowledged that they are unable to estimate cost savings at the current time.

Findings of little or no savings are not surprising in light of the recent study by Law (*Psychiatric Services*, May 2008). This study examined the experience of prior authorization policies in West Virginia and Texas. The study concluded that prior authorization policies for second generation antipsychotic medications do not appear to reduce pharmacy costs, most likely because alternative drugs are also expensive. In addition, the article suggested that the most likely avenue to achieve cost savings is through the pursuit of supplemental rebate agreements with manufacturers. Ohio is now considering this approach.

In addition to the inability of ODJFS to document any cost savings that may ensue as a result of prior authorization, it is clear that implementing a prior authorization system will impose additional costs on both medical providers (time spent on compliance) and the Medicaid managed care companies that will be forced to implement the process (additional administrative cost). Additional administrative and compliance costs occur because any responsible prior authorization policy must include procedures for permitting “subsequent” authorization by which a patient or patient’s physician can establish medical necessity for the higher cost drugs. ODJFS has stated that they anticipate approval of 90% of Medicaid prior authorization drug requests and appeals. This means that if the State could derive a marginal savings from prior authorization, those savings

would occur only with respect to 10% of the affected prescriptions. This also implies that for every potential instance of savings obtained through prior authorization, nine other instances of additional administrative or compliance burdens would occur for those patients whose physicians could establish an appropriate basis for prescribing the drug.

I. Estimated Number of ODJFS Medicaid Clients with Schizophrenia or Bipolar Disorders

National Institute of Mental Health (NIMH) estimates that 1.1% of the general population have schizophrenia and that 2.6% of the population have bipolar disorder.

<http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-america.shtml>)

Neither condition occurs disproportionately in children or in the elderly. Therefore, the application of these percentages to the non-elderly adult population does not distort the estimate of the number of persons with either condition within the 18 to 64 age group.

Census data show that Ohio has about 6.6 million persons aged 20-64. (2000 Census, U.S. Census Bureau).

The table summarizes the estimated number of such persons with either schizophrenia or bipolar disorder based on NIMH percentages.

Table 1: Estimated Number of Persons in the Ohio Population with Schizophrenia and Bipolar Disorders

	Schizophrenia	Bipolar	Total
Population Age 20-64	6,600,000	6,600,000	
Percent of Population	1.1%	2.6%	
Number of Persons	72,600	171,600	244,200

The existence of a diagnosis of schizophrenia or bipolar disorder does not automatically render a person disabled nor does such a diagnosis automatically qualify a person for Medicaid. Table 1 simply creates a context to show the size of the pool of afflicted persons from which the disabled persons with schizophrenia or bipolar disorder come. It is still necessary to determine what percentage of disabled persons who receive Medicaid actually suffer from these forms of mental illness.

ODJFS reports that about 249,000 persons qualified for Medicaid as disabled in February 2008. This total excludes children, the blind, and the aged. This total includes all causes of disability. To determine what percentage of these disabled persons have a schizophrenia or bipolar diagnosis, this analysis relied on a study from Georgia. That study found that 6% of the Medicaid population there had a diagnosis of schizophrenia. (Martin, B.C., and Miller, L.S. “Expenditures for treating schizophrenia: A population-based study of Georgia Medicaid recipients”. *Schizophrenia Bulletin*, 24(3):479-88, 1998.) Six percent of disabled Medicaid clients would equal an estimated 14,940 disabled Ohio Medicaid clients with schizophrenia. Bipolar disorder is more than two-

and-a-half times more common than schizophrenia. To make a conservative estimate, Table 2 assumes that bipolar disorder causes disability only twice as often as schizophrenia rather than two and one-half times as often, as the higher incidence of bipolar disorder in the total population would imply. If bipolar disorder only accounts for twice as many clients as schizophrenia, it adds another 29,880 disabled Medicaid recipients. Thus, the estimates here use the Georgia study to hypothesize that in Ohio about 44,820 of a total number of disabled persons of 249,000 have a mental illness diagnosis of either schizophrenia or bipolar disorder. Table 2 summarizes this estimate.

Table 2: Estimated Number of Persons in the Ohio Disabled Medicaid Population with Schizophrenia and Bipolar Disorders

	Schizophrenia	Bipolar	Total
# of ODJFS Disabled	249,000	249,000	
Percent of Population	6%	12%	
# of Medicaid Clients	14,940	29,880	44,820

The sum of clients with schizophrenia and bipolar disorder equals an estimated 44,820 persons with these conditions among the Medicaid disabled population.

These estimates provide only a rough projection. They do not include persons eligible for Medicaid because they are children, blind, or aged. A request for actual data about the number of persons with these diagnoses has been made of ODJFS. At the time of this writing, ODJFS indicated they were working on the request but had not yet provided the requested data. A comparison of the total in Table 2 to the total in Table 1 shows that about 18.35% of the total estimated number of persons with either condition in Ohio is projected as disabled (44,820 divided by 244,200 = 18.35%).

As a final step, it is important to note that the estimates here do not distinguish between fee-for-service and managed care Medicaid clients. Data from ODJFS for 2006 showed a total of 6734 individuals with bipolar disorder in the Ohio Medicaid fee For Service program. 6734 is roughly 22.5% of the figure of 29,880 bipolar individuals in the Ohio Medicaid population computed in Table 2 above. Therefore, it seems that an assumption that Fee for Service comprises 25% of the Ohio disabled Medicaid population with mental health illnesses while Managed care comprises 75% seems both reasonable and conservative. Note that the number of individuals suffering from severe depression is NOT included in these totals.

Final calculation of the number of individuals that stand to be affected by the proposed prior authorization requirement occurs in two steps. First, the figures in Table 2 can be rounded so that the 14,940 persons with schizophrenia becomes 15,000, and the 29,880 persons with bipolar disorder becomes 30,000. Second the estimated 75% managed care population percentage can be applied to these figures. Table 3 shows these calculations.

Table 3: Estimated Number of Persons in the Ohio Disabled Medicaid Population with Schizophrenia and Bipolar Disorders by Program

	Schizophrenia	Bipolar	Total
Total # of Medicaid Clients	15,000	30,000	45,000
# in Fee for Service (25%)	3,750	7,500	11,250
# in Managed care (75%)	11,250	22,500	33,750

II. Estimated Medical Costs Deriving from Adverse Effects of Prior Authorization

The final step in this analysis is to estimate the costs deriving from the adverse consequences expected to result from the imposition of a prior authorization requirement in Ohio.

A study of Maine’s experience with prior authorization by Harvard Medical School professor Stephen Sumerai (*Health Affairs*, April 2008) concluded that there was a 29% greater risk of treatment discontinuity (30 days without medication, switching of medication, or augmentation of medication) as a result of the prior authorization requirement. Because a switch in or augmentation of medication may also represent fine-tuning of therapy as well as discontinuity of treatment, the more useful finding is that there was an 18% greater risk of a patient going more than 30 days without medication as a result of the prior authorization policy change. Sumerai cites research by Gitlin (*American Journal of Psychiatry*, 2001) finding that 80% of schizophrenics suffer a relapse when they go off of their medication. Because relapses are highly correlated with adverse outcomes (such as ER visits, hospitalizations, homelessness, violence resulting in incarceration, etc.), the finding of a greater likelihood of medication gaps as a result of prior authorization can reasonably be expected to have cost consequences outside the Medicaid pharmacy budget.

Estimation of these costs occurs as follows:

1. The data presented in the Sumerai study suggest a 6 percentage point greater likelihood of a gap in medication occurring as result of prior authorization. This figure is generally consistent with findings by Weiden (*Psychiatric Services*, 2004) that showed a 5 percentage point increase in the number of psychiatric hospitalizations for schizophrenic patients with medication gaps, and with data presented in Olfson (*Psychiatric Services*, February 2000) that shows a baseline rate of medication non-compliance for schizophrenics at 19% (other studies show even higher rates).
2. Applying the above percentage to the estimated number of individuals with schizophrenia (11,250) and bipolar disorder (22,500), shown in Table 3 above, leads to an estimate of how many individuals will suffer treatment gaps as result of a prior authorization policy in Ohio. These figures are 675 for those with schizophrenia and 1350 for those with bipolar disorder for a total of 2025 affected individuals.

3. Using the Gitlin finding that 80% of those off their medication suffer a relapse leads to 540 individuals with schizophrenia and 1080 individuals with bipolar disorder. This is a total of 1620 people who are expected to have an adverse outcome as a result of prior authorization in Ohio.
4. A study by Ascher-Svanum, et. al. (International Society for Pharmaceutical and Outcomes Research, 2005) estimated that the marginal cost of a relapse for schizophrenia patients is \$21,473. Rounding this figure to \$21,500 results in an estimated additional cost to the Medicaid program of \$11,610,000 for 540 schizophrenia patients suffering relapses as a result of prior authorization policies which lead to gaps in medication. The \$21,500 cost figure for a patient with a medication gap is consistent with findings by Ziegler (*Community Mental Health Journal*, 2003) that found that switching patients from less costly older (or “typical”) antipsychotic drugs to more costly newer (or “atypical”) drugs actually resulted in *cost savings* of \$17,000 per patient per year. The reason for the cost savings from the usage of more costly drugs is that these drugs are generally more effective and/or better tolerated by patients, resulting in fewer instances of relapse, the costs of which far outweigh the higher drug expense.
5. The Ascher-Svenum cost estimate is for schizophrenia patients. No counterpart study estimated the cost of medication gaps in the treatment of bipolar disorder. However, McIntyre (*CNS Spectrums: The International Journal of Neuropsychiatric Medicine*, Nov. 2004) characterized bipolar disorder as possibly the most costly category of mental disorders in the United States. Note that the fact that bipolar disorder is more expensive than schizophrenia in *the aggregate* does not necessarily imply that treatment of bipolar disorder costs more per patient. Because for every two persons with schizophrenia, five persons have a diagnosis of bipolar disorder, the total cost for treatment of bipolar disorder could exceed the total cost for treatment of schizophrenia even though the per patient cost of schizophrenia exceeded the per patient cost for treatment of bipolar disorder. The estimates here assume that the marginal cost of a relapse for a person suffering from bipolar disorder will be 75% that for schizophrenics (\$16,125). This estimate takes a conservative approach because it does not assume that the per patient cost of bipolar disorder is as expensive as the per patient cost of schizophrenia in the absence of any evidence to that effect. At the same time, the estimate obtains a result consistent with the higher aggregate cost for bipolar disorder in comparison to the aggregate cost of schizophrenia. As a result, the estimated cost of medication gap-induced relapses for the estimated 1080 bipolar patients is \$17,415,000. This figure reflects both a conservative assumption relative to the marginal cost related to schizophrenia patients and is also consistent with the finding that bipolar disorder is more costly overall.
6. **The total estimated medical cost for schizophrenic and bipolar patients in managed care in Ohio is \$29,025,000.** Furthermore, this figure represents an underestimate because it does not include:
 - a) costs related to the severely depressed population;
 - b) costs related to fee for service patients;

- c) any costs relating to job loss, homelessness or incarceration;
 - d) patients receiving Medicaid benefits because they are “aged;” and
 - e) patients receiving Medicaid benefits under the Covered Families and Children program.
7. It is unclear whether or not the Maine prior authorization program included an exemption for prescriptions prescribed by psychiatrists. The prior authorization initiative proposed in Ohio would include such an exemption and ODJFS estimates that this would apply to 40% of the mental health prescriptions written. If the Maine system did not have such a feature then it would be appropriate to adjust all relevant percentages from the Soumerai study downward to account for this difference when applying the Maine findings to Ohio. **The result is a lower bound medical cost estimate for schizophrenic and bipolar patients in managed care in Ohio of \$17,415,000.**

In order for Ohio’s proposed prior authorization policy to make any economic sense whatsoever, ODJFS would need to show savings to the Medicaid pharmacy budget of at least \$17,415,000 and perhaps as much as \$29,025,000. Taking into account the increased bureaucratic costs of instituting a new prior authorization policy, the list above of factors excluded from this estimate, as well as the potential harm that could come to individuals as a result of such a policy, logic would dictate that the pharmacy cost savings should really be far in excess of this range in order for such a policy to be worth implementing.

8. ODJFS has recently announced its intention to pursue “supplemental rebates” from manufacturers of mental health medications. Medications supplied by any pharmaceutical company which refuses to pay a supplemental rebate to ODJFS will not be recommended for inclusion on the preferred drug list (PDL). The Pharmacy & Therapeutic committee could advise that the drug still be included on the PDL, however, their role is only advisory to ODJFS. Physicians who serve Medicaid mental health patients on a fee for service basis will be required to seek prior authorization in order to prescribe those medications excluded from the PDL. As a result, this supplemental rebate policy is very likely to have the same practical effect as extending the prior authorization requirement to the fee for service population.

Consequently, it would be appropriate to include an estimate of the impact on fee for service patients as well. Table 3 above shows that fee for service patients are estimated to be ¼ of the total. This means that there are 1/3 as many schizophrenic and bipolar patients in the fee for service setting as in the managed care setting. Because all of the cost parameters would remain the same, the estimated cost impact on fee for service patients is 1/3 of the \$29,025,000 cost for managed care patients. **Thus the estimated cost impact on the fee for service population is \$9,675,000, making the total medical cost for all schizophrenic and bipolar patients \$38,700,000.** In the event that it is necessary to adjust these estimates if Maine did not exempt prescriptions written by psychiatrists from its prior authorization requirement, the cost associated with fee for service patients would become \$5,805,000, and the total cost estimate for both fee for service and managed care patients would become \$23,220,000.

III. Estimated Social (Non-Medical) Costs Deriving from Adverse Effects of Prior Authorization

In a recent study Shern, et. al. (*American Journal of Psychiatry*, 2008) concluded that “for adults with severe mental illness, it appears that efforts to contain Medicaid mental health costs may result in deflecting costs back to these vulnerable persons and onto their families and friends”. The areas identified below provide examples of these types of costs.

1. Lost Wages – One of the most significant problems for individuals who suffer from severe mental illness is the inability to work. Mental health advocates estimate that roughly 9 out of every 10 individuals with a serious mental illness is unemployed. A recent study by Kessler (*American Journal of Psychiatry*, May 2008) estimates at least \$193 billion annually in lost earnings by those who suffer from “serious mental illness” (SMI) in the United States. This research was funded by the National Institutes of Health. SMI is a more general category than schizophrenia or bipolar disorder, although it could include both diagnoses. The Kessler study defined the occurrence of an SMI when a person with a mental illness loses 30 days or more of work during a year due to that illness. In other words, the study identified as “serious” those mental illnesses which cause a person to lose at least 30 days of work in a year. Since Ohio’s population equals slightly more than 3% of the U.S. total population, the \$193 billion in lost wages nationally implies an estimated \$6 billion in lost wages in Ohio. The marginal per person loss in wages appears to equal about \$16,000 for those who suffer an SMI during the year.

Item #3 in Section II, above, estimates that 1,620 Medicaid patients will suffer a relapse due to prior authorization policies. If these relapses also met the criteria for SMI, the cost in lost wages for each relapse would average about \$16,000. This implies a maximum total of lost wages of about \$26 million ($1,620 \times \$16,000 = \25.9 million). This amount probably overestimates the number of relapses which cost 30 days of work and also overestimates the wage level of Medicaid recipients. No data exist to connect the Kessler study to the Ascher-Svanum study. Nevertheless, it does appear reasonable to assume that if even a small percentage of additional relapses qualify as SMI, their marginal effect on wages could translate into millions in lost wages.

2. Homelessness – Estimates have suggested that 30% of homeless Ohioans have a mental illness. Research by Joyce West suggests that 3.1% of persons with a discontinuity in drug therapy will become homeless. This implies that the increased risk of lapsed treatment totaling 2025 persons would translate into 63 additional cases of homelessness. Data from the National Alliance Against Homelessness show that the average annual cost of emergency shelter for a homeless individual was approximately \$8000 in 1994 (<http://www.endhomelessness.org/section/tools/tenyearplan/cost>). Assuming a 3% annual increase in this cost would bring this figure to roughly \$12,000 in 2008. No data were available to estimate the average length of homelessness attributable to lapsed drug therapy.

3. Incarceration – Data from the Ohio Department of Rehabilitation and Corrections (DRC) indicates that the cost of incarceration averages about \$25,000 per inmate per year (April 2008 DRC Fact Sheet). No data was available on which to base an estimate of the average duration of additional instances of incarceration attributable to lapsed treatment for mental illness. However, DRC has estimated that 12% of inmates are diagnosed as seriously mentally ill and that in 2006 the department spent roughly \$60 million providing mental health services to inmates. In 2006, Ohio prisons incarcerated roughly 50,000 inmates. Twelve percent of 50,000 inmates would equal 6,000 inmates with a diagnosis of serious mental illness. Consequently, the average cost of providing mental health services in the correctional system is roughly \$10,000 per person. (Note that these estimated costs for treatment of mentally ill inmates or for incarceration itself apply only to those incarcerated in State correctional facilities and do not include any such costs associated with incarceration in local jails.) Other associated costs not included in the cost of incarceration itself would involve additional demands placed on the law enforcement and criminal justice systems.

Summary Table: Estimated Net Cost of Prior Authorization

Category	Cost Savings	Additional Cost
Savings in Medicaid Pharmacy Cost	Dependent on Rebates	
Additional Administrative Cost (reviewing PA requests)		Positive but Unclear
Additional Compliance Cost by Providers (time spent by providers)		Positive but Unclear
Medical costs of schizophrenic and bipolar patients		\$17,415,000- \$29,025,000
Medical costs of severely depressed patients		Not estimated
Medical costs of fee-for-service patients if supplemental rebate plan implemented		\$5,805,000 - \$9,675,000
Cost of lost wages of the severely mentally ill		\$16,000 per person
Average cost of emergency shelter for a homeless person for one year		\$12,000 per person
Average cost of providing mental health services in correctional facility for one year		\$10,000 per person
Average cost of housing an inmate in a correctional institute for a year		\$25,000 per person
Total	Unknown	\$23,220,000 - \$38,700,000