KANSAS MENTAL HEALTH COALITION

An Organization Dedicated to Improving the Lives of Kansans with Mental Illnesses

Testimony presented to the House Health and Human Services Committee on SB 341

Amy A. Campbell – March 10, 2016

Thank you for the opportunity to address your committee today on behalf of the Kansas Mental Health Coalition (KMHC). The Kansas Mental Health Coalition is dedicated to improving the lives of Kansans living with Mental Illnesses and Severe Emotional Disorders. We are consumer and family advocates, provider associations, direct services providers, pharmaceutical companies and others who share a common mission. At monthly roundtable meetings, participants develop and track a consensus agenda that provides the basis for legislative advocacy efforts each year. This format enables many groups, that would otherwise be unable to participate in the policy making process, to have a voice in public policy matters that directly affect the lives of their constituencies. The opportunity for dialogue and the development of consensus makes all of us stronger and more effective in achieving our mission.

The Kansas Mental Health Coalition opposes SB 341 as written - removing the prohibition against step therapy in the Medicaid program in Kansas. Step therapy requirements are also known as "Fail First" policies – requiring the individual to first "fail" on a number of other medications.

Step Therapy Policies Should Not Include Mental Health Medications

Research indicates that fail first policies can have devastating consequences when patients face rejection of their prescription at the pharmacy counter.

Every public description of this new policy by the administration has indicated that the step therapy proposal would not apply to mental health medications. Unfortunately, the language of SB 341 removes the only statutory protection that exists. This could be corrected by inserting the step therapy prohibition language into K.S.A. 39-7,121b – see attachment. When KMHC presented our concerns about the inconsistency between the bill language and these public statements in January, KDHE drafted an exclusion amendment. We support that amendment. See attached.

Many mental health consumers need medication to recover, to alleviate symptoms and to make the illness "manageable". Access to the full range of FDA approved medications, including those that are new and those most effective promotes successful treatment. Continuity of the medication regime is essential. Finding and maintaining the most effective medications is often the key to a durable recovery that enables children with mental illness to attend school and graduate, enables adults to keep jobs and contribute to their communities, and enables families to stay together.

Research indicates that fail first policies can have devastating consequences when patients face rejection of their prescription at the pharmacy counter. If private insurance policies are allowed to use step therapy for mental health drugs, why should we worry about step therapy in Medicaid? Medicaid consumers do not have the same degree of resources and access to professionals as the average private insurance consumer or even a Medicare consumer in order to navigate the complications of medication restrictions. It is unlikely they will know they are entitled to temporary prescriptions or to know if they are supposed to be "grandfathered" when they suddenly find their prescription can't be filled at the pharmacy. Furthermore, private insurance policies do not have to pick up the costs of serving people

who end up in jails. Individuals who leave treatment and decompensate rarely maintain private insurance, and ultimately their care and treatment falls to the public mental health system and state mental health hospitals.

Please recognize that many states have restrictions on the use of step therapy. A few examples are listed here.

Medicare Part D (prescription drug) plan formularies must include substantially all drugs used to treat a wide range of conditions and diseases, **including depression, psychoses, convulsions, cancer, and AIDS**. (See 42 C.F.R. §423.272(b)(2) and Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.2.5.)

Indiana Medicaid. With certain exceptions, Indiana law prohibits prior authorization requirements under the state's Medicaid program for mental health drugs, such as antianxiety, antidepressant, or antipsychotic drugs.

Michigan Medicaid. The law prohibits a prior authorization requirement for anticonvulsants, antidepressants, antipsychotics, or an antianxiety drug in a generally accepted standard medical reference that is not a controlled substance.

New York Medicaid passed as part of the FY 14 budget establishes a "prescriber prevails" provision in the state's Medicaid Managed Care program. The provision applies to medically necessary prescription drugs in the anti-depressant, antiretroviral, anti-rejection, seizure, epilepsy, endocrine, hematologic, and immunologic therapeutic classes, including non-formulary drugs. It requires insurers to cover those drugs that are medically necessary and warranted in the prescriber's reasonable professional judgment. The prescriber must consult with the managed care provider in making this decision.

This is not a comprehensive list, and it also does not include restrictions on private insurance plans.

If it is the will of this committee that step therapy policies be implemented, please amend this bill to include minimum patient protections.

In Connecticut, PA 13-234 allows the DSS commissioner to establish a step therapy program for prescription drugs in the Medicaid program. It allows him to condition payment for these drugs on a requirement that the drug prescribed be from the state's PDL before any other drug being prescribed. If implemented, any step therapy program must:

1. require that the patient try and fail on only one prescribed drug on the PDL before another drug can be prescribed and eligible for payment;

2. not apply to any mental health–related drugs; and

3. give the prescribing practitioner, when medications for the treatment of any medical condition are restricted due to the step therapy program, access to a clear and convenient process to expeditiously request an override by DSS of the restriction.

Under the act, DSS must expeditiously grant an override if the prescribing practitioner demonstrates that:

1. the preferred treatment required under step therapy has been ineffective in the treatment of the patient's medical condition in the past,

2. the drug required under the step therapy program is expected to be ineffective based on the patient's known relevant physical or mental characteristics and the known characteristics of the drug,

3. the preferred treatment required under the step therapy program will cause or will likely cause an adverse reaction or other physical harm to the patient, or

4. it is in the best interest of the patient to provide the recommended drug regimen based on medical necessity.

The step therapy program requirement may not run longer than 30 days, after which the prescribing practitioner may deem the treatment to be clinically ineffective for the patient. If he or she does this, the drug prescribed and recommended by the practitioner must be dispensed and covered under the Medicaid program.

According to DSS, the step therapy procedures are an extension of existing prior authorization protocols for requesting a drug not on the PDL. When a pharmacy submits a bill for a drug not on the PDL, the pharmacy benefit manager automatically looks back in the person's claims history to see if he or she has previously tried a preferred product. If he or she has, the system will automatically approve the drug that is not on the PDL without requiring the prescriber to obtain prior authorization. If the claims system does not show the use of the preferred product, the prescriber must obtain a prior authorization and justify why the non-preferred product is needed. But, if prior authorization is not obtained, the pharmacy can provide a one-time 14-day supply until the prescriber requests and obtains a prior authorization. Once this authorization is obtained or the prescriber decides the individual can use the preferred product, the individual will be able to obtain their next refill after using their 14-day prescription.

Mental Health Medication Advisory Committee History and Concerns

Last session, the Legislature adopted Sub for HB 2149 which amended the statutory protection from restrictions on access to Medicaid mental health medications. It created the Mental Health Medications Advisory Committee to recommend prescribing policies to the Medicaid Drug Utilization Review Committee. At this point, there are a number of proposed policies moving their way through the process. There has not yet been time to implement these policies. There has not been time to test the proposed safety measures that were promised for mental health consumers – including extended temporary prescriptions and expedited uniform approval processes by the managed care organizations.

The Advisory Committee was created through agency conversations with a stakeholder work group that created new statutory language for K.S.A. 39-7,121b. In addition, this work group developed "guard rails" – basic operational guidelines – for how the Advisory Committee would work and how prior authorization policies would be implemented.

The last version we received of the guard rails is as follows:¬

- Patients who are already on stable, safe regimens will be able to continue their prescribed treatment.
- Creation of a Mental Health Medication Advisory Committee made up of mental health practitioners and pharmacists with specific experience in providing service to the mental health community.
- Review certain medications for safety and dose optimization.
- New prescriptions or changes in medication will be subject to evidence-based guidelines developed by the Drug Utilization Review Board with the counsel of the Mental Health Medication Advisory Committee.
- Increase length of emergency prescription fills from 3 days to 5 days to allow for processing time in situations where prior authorizations are required and assure that these are paid to the pharmacies. • Hold the number of prior authorizations needed to a minimum, while still providing for the appropriate protections.
- The three MCOs will be required to follow policies set by the state, and no changes to the current system will be allowed until such time that policies are put in place to assure minimal disruptions to providers and patients.

The Coalition was very pleased to finally see some collaboration on the initiative and supported the creation of the MHMAC. Unfortunately, these principles are only guidelines and will likely not survive beyond the next change of administration or agency leadership. In fact, they don't seem to be printed anywhere for the public. It would have been better to have them included in the statute.

The Kansas Mental Health Coalition commends the members of the MHMAC for the work accomplished to date, and their amount of time spent discussing how prior authorization policies can be implemented carefully to minimize potential harm to the Medicaid member. However, we have serious concerns.

A key to the success of mental health prescription policies lies in "process improvement initiatives", which have been discussed, but are being handled outside the Committee itself. These include uniform procedures by all three MCOs to minimize disruption and time taken away from patients and, development of preferred provider status for expert prescribers. Most of the settings where Medicaid patients are served operate with minimal staffing. The public mental health system constantly struggles with finding qualified mental health professionals.

These processes will be the key to whether or not the implementation will be a positive or negative experience to Medicaid providers and participants.

KMHC offered concerns and recommendations at a January meeting of the House Social Services Budget Committee to improve the MHMAC:

Concerns:

- The ability of the public to participate meaningfully in the MHMAC meetings is limited by the lack of information available. The public is unable to access the language of proposed policies nor the list of medications included in the proposed policies in order to provide informed public comment. After the committee has discussed a proposed policy, we are unable to get a copy of the proposal as discussed nor as amended. Even after policies were approved by the MHMAC to be forwarded to the Medicaid DUR Committee, the policies were not posted. Policies approved in January by the Medicaid DUR Committee are still not available.

- MHMAC meeting agendas are posted 14 days in advance and public comment is required to be submitted 7 days in advance. This means that if you are sitting in the audience and would like to share information during the public comment portion of the meeting, you are not allowed to speak unless you have sent in written comments 7 days in advance.

Recommendations:

- The MHMAC should have the ability to approve and revise process initiatives to assure good implementation with minimal disruption.

- We encourage the agency to bring forward supporting evidence for proposed policies, beyond simply citing the number of program participants affected. At this point, the Committee has only tackled the "low hanging fruit". We look forward to seeing well supported safety proposals for young children and older adults as well.

- Policy proposals, including a list of medications, should be posted before and after meetings – these can be clearly marked "DRAFT".

After hearing our suggestions, the agency made positive suggestions for changing the committee meetings to allow for public input, but other issues have not yet been addressed.

Until the MHMAC has proven its capability to implement successful prior authorization policies based on effectiveness and safety, the Kansas Mental Health Coalition cannot endorse the consideration of step therapy policies – which focus only on drug costs.

The Kansas Mental Health Coalition is committed to working with the Department on Health and Environment and the Legislature to continue to promote safe, positive policies for prescribing. Please do not adopt SB 341 as written.

Thank you for your consideration.

For More Information, Contact:

Kansas Mental Health Coalition
c/o Amy A. Campbell, Lobbyist
P.O. Box 4103, Topeka, KS 66604
785-969-1617; fx: 785-271-8143, campbell525@sbcglobal.net

39-7,121b. Limitations on restrictions on medications used to treat mental illness; medications available without restrictions; review by mental health medication advisory committee and medicaid drug utilization review board; mental health medication advisory committee established; members; meetings. (a) No requirements for prior authorization or other restrictions on medications used to treat mental illnesses may be imposed on medicaid recipients, except on medications subject to guidelines developed by the medicaid drug utilization review board according to subsection (b). None of the following shall be construed as restrictions under this subsection:

(1) Any alert to a pharmacist that does not deny the claim and can be overridden by the pharmacist;

(2) prescriber education activities; or

(3) the consolidation of dosing regimens to equivalent doses.

(b) The mental health medication advisory committee shall provide recommendations to the medicaid drug utilization review board for the purpose of developing guidelines. The medicaid drug utilization review board may accept the recommendations of the mental health medication advisory committee in whole and such recommendations shall take effect immediately upon such approval. The medicaid drug utilization review board may reject the recommendations of the mental health medication advisory committee in whole and such recommendations shall be referred back to the mental health medication advisory committee for further consideration. No medication guidelines related to mental health medications shall be adopted by the medicaid drug utilization review board without recommendations made by the mental health medication advisory committee.

(c) For the medications used to treat mental illness that are available for use on July 1, 2015, the medicaid drug utilization review board shall review all such medications prior to July 1, 2016. For medications used to treat mental illness that do not exist on July 1, 2015, but are later developed or believed to be effective in the treatment of mental illness, the medicaid drug utilization board shall review all such medications within six months of presentation to the medicaid drug utilization review board.

(d) Neither the department of health and environment nor the mental health medication advisory committee shall implement any program to require that a recipient has utilized or failed with a drug usage or drug therapy prior to allowing the recipient to receive the product or therapy recommended by the recipient's physician.

(e) The mental health medication advisory committee is hereby established.

(1) The mental health medication advisory committee shall be appointed by the secretary of health and environment and consist of nine members; including the secretary of health and environment, or the secretary's designee, who shall be the chair of the committee; two persons licensed to practice medicine and surgery with board certification in psychiatry nominated by the Kansas psychiatric society, one of whom specializes in geriatric mental health; two persons licensed to practice medicine and surgery with board certification in psychiatry nominated by the association of community mental health centers of Kansas, one of whom specializes in pediatric mental health; two pharmacists nominated by the Kansas pharmacists association; one person licensed to practice medicine and surgery nominated by the Kansas medical society; and one advanced practice registered nurse engaged in a role of mental health nominated by the Kansas state nurses association. All nominating bodies shall provide two nominees for each position for which they provide nominations, with the secretary selecting the appointee from the provided nominees.

(2) The mental health medication advisory committee shall meet upon the request of the chair of the mental health medication advisory committee, but shall meet at least one time each quarter.

(3) Members of the mental health medication advisory committee are entitled to compensation and expenses as provided in K.S.A. 75-3223, and amendments thereto. Members of the committee attending committee meetings shall be paid mileage and all other applicable expenses, provided such expenses are consistent with policies established by the secretary of health and environment.

History: L. 2002, ch. 180, § 2; L. 2015, ch. 63, § 4; July 1.

Amendment drafted – KDHE – 1-28-16

Section 1. K.S.A. 39-7,121 is hereby amended to read as follows: (a) The department of health and environment shall establish and implement an electronic pharmacy claims management system in order to provide for the on-line adjudication of claims and for electronic prospective drug utilization review.

(b) The system shall provide for electronic point-of-sale review of drug therapy using predetermined standards to screen for potential drug therapy problems including incorrect drug dosage, adverse drug-drug interactions, drug-disease contraindications, therapeutic duplication, incorrect duration of drug treatment, drug-allergy interactions and clinical abuse or misuse.

(c) *With respect to drugs prescribed for behavioral or mental health conditions*, the department of health and environment shall not utilize this system, or any other system or program to require that a recipient has utilized or failed with a drug usage or drug therapy prior to allowing the recipient to receive the product or therapy recommended by the recipient's physician.

Section 2. K.S.A. 39-7,121 is hereby repealed in its entirety.

Section 3. This act shall take effect and be in force from and after its publication in the statute book.