



FLORIDA'S COALITION FOR OPEN ACCESS

Providing a Clinically Sound Preferred Drug List in Florida with Budget Restraints

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“Given the rapid increase in the use of PA policies and other cost control mechanisms in Medicaid, the relative lack of data on their risks and benefits is cause for concern. It is sobering to realize that if such policies were considered for a clinical study, the possible risks of reduced access to essential medications would likely result in a failure to obtain human-subject approval from most institutional review boards (IRBs). These policies can be viewed as massive experiments on vulnerable populations.” Benefits and Risks of Increasing Restrictions on Access to Costly Drugs in Medicaid, Stephen Soumerai, Health Affairs, Volume 23, Number 1

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INTRODUCTION:

The Florida Coalition for Open Access (“Coalition”) will mobilize public awareness of and interest in a critical topic for Florida. That is the challenges facing the Florida Agency for Health Care Administration (“AHCA”) and its statutory Pharmaceuticals and Therapeutics Committee (“Committee”). Those challenges are to keep a suitable and effective Preferred Drug List while facing budgetary restraints. In these considerations vulnerable humans become at risk while restrictive conditions can increase Medicaid wide expenses if the limits are not cost-effective. We do not want patients getting sicker and needing more expensive care as a result of management of our Preferred Drug List or poor Prior Authorization practices.

In Medicaid “...coverage of prescription drug benefits is a ‘good deal’ – that the provision of this benefit can help to keep enrollees healthier and potentially prevent more serious and/or costly medical interventions.”¹

There are budgetary pressures to remove or restrict accessibility to certain drugs to save specific transaction costs. Doing this without considering outcomes to patient care or costs to the Medicaid Program (“Program”) can do more harm than good. The Coalition commits to help the Committee get the good deal of an effective pharmacy while finding the best ways to deal with budget restraints. Doctors, psychologists, provider organizations, advocates, consumers, and taxpayers can all contribute to this for the people of Florida. Public awareness can help guide what is the best solution in various cases.

The first work of the Florida Coalition for Open Access (“Coalition”) focuses on drugs for mental health. The following principles guide the Coalition’s efforts.

- No single drug is effective for all patients. Given significant individual variability in response, all marketed antipsychotic medications should be available to patients who need treatment with them.² The Preferred Drug List should include all mental health medications for the most cost-effective clinical circumstances.
- There are no known therapeutic substitutions for antipsychotic medications.
- The doctor and patient should select the best pharmacological agent. This should be after consideration of patient needs, settled practice standards, affordability, comorbidities, drug interaction considerations and best evidence practices.
 - Doctors should have the choice to note “Dispense as Directed” or “no substitution” on prescriptions
 - Shared cost requirements are not proper for a needs based population.
- Education should inform providers, beneficiaries and their families, and the public and its elected representatives. They should learn about the issues facing the Committee’s members, best evidence practices and practice standards in the use of particular medications.
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- No denial of or medically dangerous delay in providing needed medication to a beneficiary is acceptable.
- “Fail First” efforts to direct a patient to a less expensive drug before using the preferred drug can be dangerous. This should not occur for an individual without evidence it will not cause the patient harm. It is not acceptable to switch a patient stabilized on a specific medication to another medication for only specific transaction cost savings.

¹“Prescription Drug Coverage Under Medicaid,” Updated March 12, 2004, Congressional Research Service, The Library of Congress.

²“Principals of Antipsychotic Prescribing for Policy Makers, Circa 2008. Translating Knowledge to Promote Individualized Treatment,” National Association of State Mental Health Program Directors.

- Removal of a particular medication from the Preferred Drug List of a particular medication should only happen when there is an overall benefit
 - To patients to assure correct use, and
 - To the Program by considering overall cost outcomes of using Prior Authorization.
- Prior Authorization, where needed, must be fast, efficient, and finally be for the best interest of patients. It should not be a limit of access to cost-effective therapies for those who need them.³ Independent monitoring of a prior authorization procedure will assure it is not resulting in inappropriate denial or delay of care.
- Utilization Management strategies best respond to the challenges faced in providing prescription drug benefits. They should include input from practicing psychiatrists and other mental health providers, consumers, and the public. There should be a Center for Applied Psychopharmacology set up, funded from rebate savings in negotiated Preferred Drug List pricing and other available grants. This Center can inform the Committee and other interested parties. It can leverage on the existing medical and psychology resources of Florida's University System and its related units.

DISCUSSION:

Well-recognized conditions challenge the Committee. Demands for Medicaid benefits are increasing. Costs for many newer medications are more expensive than older medications. Especially in mental health practice, experience tells us that one drug does not fit all patients.⁴

...medicine is very individualized and, in certain classes of medication, no two patients may react or respond the same way. This phenomenon is known as heterogeneity of response.⁵

The literature expresses strong concern about denial or delay of proper medications. They are dangerous for patient care and can increase costs to the Program because of avoidable acute care that becomes necessary as a result. Using newer drugs can reduce hospital stays. Insisting on generic drug use only can (because generics are typically older) increase total treatment costs and leads to worse outcomes.⁶

“...overall medical costs and use of services among people who had mental illness and were uninsured revealed that continuity of medication therapy resulted in a 65 percent reduction in emergency costs and an overall mean costs savings of \$166 per patient per month.”⁷

“Ultimately, a variety of treatment options is a critical component of any prescription drug program that is designed to improve patient health and continue to reduce costs in other areas in the healthcare system.”⁸

Florida needs to study how these concerns affect our own state.

The Committee faces the balancing act of providing necessary and appropriate medical care while containing rising costs. See Fla. Statutes §409.91195 and 409.12(39) (a) (especially 409.12(39) (a) (10)). They create a basis for fair and humane decisions while saving money for all Floridians.

³ Id.

⁴ “Preferred drug lists: Potential Impact on Healthcare Economics,” *Vascular Health and Risk Management* 2008:4(2) 403-413.

⁵ Id.

⁶ Lichtenberg, F.R. (Winter 2003). New Drugs: Health and Economic Impacts. *National Bureau of Economic Research Reporter*.

⁷ Del Paggio, D. Finley, and Cavano J. (2002). Clinical and economic outcomes associated with Olanzapine for the treatment of psychotic symptoms in a county mental health population. *Clinical Therapeutics*, 24.5, 803-817.

⁸ Hunter, D. (May 2003). Government Controls on Access to Drugs: What Seniors Can Learn from Medicaid Drug Policies. *The Heritage Foundation Backgrounder*, No. 1655.

The Committee's statutory mandate from the Florida Legislature is this. "... develop its preferred drug list recommendations by considering the clinical efficacy, safety, and **cost-effectiveness** (emphasis added) of a product." Fla. Stat. §409.9115(8).

Note that being cost-effective does not mean that the strategy saves money, and just because a strategy saves money doesn't mean that it is cost-effective.⁹

Guidance for the Committee's difficult task is available from The National Association of State Mental Health Program Directors ("NASMHPD"). See "Principles of Antipsychotic Prescribing for Policy Makers, Circa 2008. Translating Knowledge to Promote Individualized Treatment." It contains, with an analysis of recent research about antipsychotic medications, a "Statement on Comparative Effectiveness of Antipsychotic Medications and Individualized Treatment" ("Statement"). The Statement sets up "General Principles of Antipsychotic Access, Efficient Utilization, and Prescribing.":

1. Treatment with antipsychotic medication, like any other treatment, should be individualized in order to optimally promote recovery.
2. Treatment with antipsychotic medication should be as effective, safe and well tolerated as possible.
3. Treatment with antipsychotic medication should consider personal preferences and vulnerabilities.
4. Treatment with antipsychotic medication should provide value in terms of improved quality of life to the consumer.
5. Treatment choices should be informed by the best current evidence and must evolve in response to new information.
6. **Cost considerations should guide antipsychotic medication selection once the preceding principles are met.** (emphasis added)

The Statement makes clear the policy recommendations are not support for:

- step therapy,
- having only a single atypical as a preferred drug list choice, or
- requiring trials of one of the minimum choices recommended for PDLs before authorization to try the others.

The Coalition agrees with the Statement and interpolates the principles to apply to all recipients and medications. Similar standards could apply to ADHD medications, antidepressants and others. In other words, cost savings are a consideration, but only after there is assurance of appropriate patient care. This is especially the case for any pharmaceutical where there is heterogeneity in response of the population(s) served.

CALLS TO ACTION:

The Coalition makes the following calls to action to assure there is appropriate medical care for Medicaid beneficiaries while facing the challenges of budget restraints.

- The best course is an open Program to provide the most cost-effective results. Where Prior Authorization is imposed anyway we agree with the Statement. The state Medical Directors assert "...access to any antipsychotic must ultimately be available through a responsive, user friendly and timely process." To that end the Committee should insist, before a medication is removed from the Preferred Drug List ("PDL"), on the following.
 - There is proof the removal and requirement for prior authorization is not dangerous to patients. Vulnerable patients should not be the subjects of experimentation if Prior Authorization works.

⁹ "Primer on Cost Effectiveness," *Effective Clinical Practice*, American College of Physicians, September/October 2000.

- Only qualified medical personnel knowledgeable about the patient's full medical history should make frontline Prior Authorization decisions.
- Any Prior Authorization process must be demonstrably compliant with the standards set out in the Statement.

There must be monitoring to discover if the Prior Authorization process is compliant with the Statement and the Settlement.

- There will be compliance with the terms of the settlement agreement filed in Hernandez et al v. Medows, United States District for the Southern District of Florida, Case No.: 02-20964 Civ. ("Settlement")
- A foundation for saving money without damage to health is possible. Adopt and develop practice standards and best evidence practices for prescriptions of all medications where there are specific concerns about costs and suitable use. Appropriate use of medications is the best course for cost-effectiveness in prescribing. Without this foundation efforts at savings will be more ad hoc, not cost-effective, and endanger the health of patients.
 - A Center for Applied Psychopharmacology should do this work. Rebate savings and other grants can fund such a center. It can then inform Florida Medicaid about utilization outcomes in Florida. Providers can report the data needed for the work of such a Center. As a result real data and analysis about Florida outcomes can inform decisions. Then the Committee can target real cost savings without giving up cost-effectiveness and proper patient care.
- There must be a comprehensive education and compliance improvement program. This will ensure that providers, patients, families, policy makers and elected representatives, and other stakeholders better understand best practices and practice standards. A benefit to providers for achieving a proved knowledge base can assure buy-in.

UNDERTAKINGS:

The Florida Coalition for Open Access undertakes to support the efforts of the Committee in the following ways:

- The Coalition will inform stakeholders and the public about the important considerations of the Committee.
- The Coalition will watch administration of the Preferred Drug List; especially to see if Prior Authorization procedures comply with the Statement and the Settlement.
- The Coalition will provide Committee members information about affects of Preferred Drug List decisions on Medicaid beneficiaries and other stakeholders.
- The Coalition will support various methods of creating enough practice standards and best evidence practices to build the foundation for a cost-effective Preferred Drug List. To that end, the Coalition will advocate for establishment of a Center for Applied Psychopharmacology to do that work.
- The Coalition will support various methods of educating providers and other stakeholders about developments in best evidence practices and practice standards.

- The Coalition will update this paper periodically and as developments call for it.

CONCLUSION:

The prescription drug benefit program is a critical ingredient of Medicaid. It delivers the most cost-effective therapies for chronic illness. Tremendous cost savings to Medicaid can result from assuring all beneficiaries get the appropriate medications needed. Therefore, full public and stakeholder awareness is essential for good outcomes from decisions of the Committee. While a budget crisis stresses a focus on specific transaction costs; cost-effectiveness does not call for denying medicines and care for the ill. Also, any such denial is self-defeating because of cost increases in other parts of Medicaid. This important public function needs full exposure to all inputs possible so beneficiaries and all other Floridians are served.

Florida's Coalition for Open Access stands ready to serve the public interest and help AHCA and the Committee to that end.