

LAW OFFICES

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August 16, 2011

**VIA HAND DELIVERY**

Mr. Neville Wise, Acting Commissioner  
Cabinet for Health and Family Services  
Department for Medicaid Services  
Office of the Commissioner  
275 East Main Street, 6<sup>th</sup> Floor  
Frankfort, Kentucky 40621-0002

Dear Commissioner Wise:

This letter is written on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) to provide comments as Kentucky transitions Medicaid patients to managed care. PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures.

Kentucky has moved to a managed care model for Medicaid patients that will utilize elements of traditional capitated managed care delivered by a managed care organization (MCO). As stated in previous correspondence, PhRMA urges Kentucky to incorporate patient protections into its guiding regulations and managed care contracts to ensure that patients have a seamless transition to managed care and that they are able to continue their current treatment regimens. As stated in our previous letter, attached for your convenience, we suggested the following patient protections:

- a Pharmacy and Therapeutics Committee that benefits patients
- a formulary designed to address the needs of Medicaid beneficiaries
- continuity of care to preserve current drug treatment regimens to preserve the stability of treatment and to minimize side effects
- prior authorization standards, and
- standards for other formulary management and utilization tools.

These patient protections ensure that patient treatment is not unnecessarily disrupted by bureaucratic decision-making. Patient health and well-being should be the focal point for all

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decisions regarding drug treatment regimens. Patients who do not get the right medicine, based on cost determinations of managed care preferred drug lists, may not only suffer medically, but may also require more costly treatment in the short- and long-term. Interfering with physician-prescribing authority subjects patients to unnecessary and potentially costly risks.

The move to managed care raises quite a few questions, the answers to which are important to our members as well as beneficiaries. Regarding the Pharmacy and Therapeutics Committee, it is our understanding that the MCO meetings will be subject to Kentucky's open meetings and open records laws. We would like to know where and how often these meetings will take place, who will be on the committees, how the current Pharmacy and Therapeutics Committee will function and how it will function vis-a-vis the MCOs and the process(es) by which pharmaceutical products will be reviewed. Will the MCOs be required to have a Kentucky specific formulary or can it be part of their national formulary? It would be beneficial to all involved if the formularies could be aligned in some manner and be available on a web page designed to provide information about, and perhaps a comparison of, access to pharmaceutical products.

Questions have also been raised about how access will be maintained for injectible drugs administered by physicians to their patients in an outpatient setting. Current state regulation permit Medicaid providers to "buy and bill" these drugs to ensure their safe administration and avoid the dangerous situation of patients "brown bagging" a drug from a pharmacy to a physician's office. Will MCOs offer this coverage under the medical benefit as well? Will all FDA-approved injectibles be available in the outpatient setting for all Medicaid recipients, including those covered by an MCO and those remaining in fee-for-service? How quickly will the Department require MCOs to add new injectible medicines to the list of covered drugs under the MCO medical benefit?

Will the Cabinet continue to set policy as reflected in current regulation or will the MCOs be exempt from current regulatory processes and rules regarding coverage, payment and appeals processes? This is particularly important regarding prior authorization and the process(es) by which decisions will be made.

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Shortly, we will call to schedule a meeting to discuss these issues. We would appreciate a response in writing. Thank you for your prompt attention to these matters.

Sincerely,



Marie Alagia Cull

MAC/tgl  
Enclosure

cc: Thomas Hardaway  
Sharon Brigner  
Gordon Rosenberry  
Walter Gose

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June 17, 2011

VIA HAND DELIVERY

Ms. Janie Miller, Secretary  
Cabinet for Health and Family Services  
275 East Main Street, 5<sup>th</sup> Floor-West  
Frankfort, Kentucky 40621

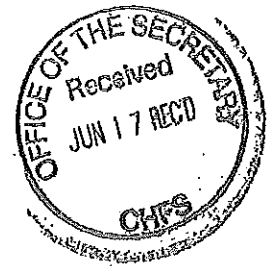
RE: Consumer and Patient Protections for  
Medicaid Managed Care Enrollees

Dear Secretary Miller:

This letter is being written on behalf of my client, The Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier and more productive lives. PhRMA's mission is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by biopharmaceutical research companies.

Please include the following consumer and patient protections for Medicaid Managed Care enrollees in your discussions with Managed Care Organizations (MCOs):

1. Maintenance drugs prescribed within the last six months should be continued for as long as the patient's physician continues to prescribe the medication even if the drug would otherwise be non-preferred or subject to a prior authorization requirement;
2. MCOs should cover all, or substantially all, drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral and antineoplastic classes, or at least those classes that are included or carved out of Kentucky's Medicaid Preferred Drug List;
3. Require review by Kentucky's Pharmacy and Therapeutics Committee of the MCO formularies;
4. Medicaid enrollees should be allowed to select the MCO formulary that best suits their medical needs. All plans and their formularies should be made publicly available to



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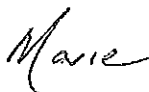
RE: Consumer and Patient Protections for  
Medicaid Managed Care Enrollees

patients, including posting on the plan website so that patients can make appropriate health care decisions;

5. Medicaid MCO formularies should be no more restrictive than the coverage provided under the Medicaid fee-for-service program;
6. The use of medical or formulary management tools should be based on industry standards, as well as the appropriate guidelines from expert patient and provider organizations. A plan should provide response within 24 hours of a request for prior authorization or override of other medical management tools; and
7. Kentucky should prepare a report assessing beneficiary access no later than January 1, 2012. The study should assess the impact of managed care on patient access to care, new barriers to the use of services, including prescription drugs, created by the use of medical management or cost containment tools. The report should analyze the impact on utilization of services, quality of care and patient outcomes. The report should also examine the use of prior authorization and other plan management tools and assess whether these tools pose an undue administrative burden for physicians, the MCO or create barriers to needed care. This report should be submitted to the Kentucky legislature, be posted on the Medicaid website and be subject to public comment.

Thank you for the opportunity to express PhRMA's position on this important transition. If you have any questions, feel free to contact me.

Sincerely,



Marie Alagia Cull

MAC/tgl

cc: Thomas C. Hardaway  
061711 Miller LTR/PhRMA/DOCS