

August 30, 2006

Jill Brown
Office of Legal Services
275 East Main Street, 5W-B
Frankfort, Kentucky 40601

RE: 907 KAR 1:604. Recipient cost-sharing

Dear Ms. Brown:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our concern with the new emergency regulations related to recipient cost-sharing. In particular, we are concerned with the implementation of a five percent (5%) co-insurance for third tier non-preferred brand name drugs.

BIO is the national trade association for the biotechnology industry, representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. Our members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products, with over 300 biotech drugs in clinical development addressing cancer, heart disease, Parkinson's, Alzheimer's and other intractable diseases.

BIO appreciates Kentucky's efforts to improve the quality of healthcare for the Medicaid population, and we are committed to assisting the state in ensuring that all patients receive appropriate and necessary health services. We are concerned, however, that the third tier prescription co-insurance included in the KyHealth Choices administrative regulations poses significant practical challenges for vulnerable patients seeking to access our innovative biologic therapies. BIO recognizes the financial constraints challenging Kentucky. At the same time, state efforts to rein-in escalating costs associated with administering the Medicaid program should not be at the expense of patients currently benefiting from life-saving medicines being developed by biotechnology companies.

BIO wants to ensure that patients are not over-burdened by financial constraints. Physicians should be able to prescribe the most appropriate therapy for an illness in balance with states' attempts to curb prescription drug and overall health costs.

That said, we are greatly concerned about the feasibility of obtaining prescription drugs when the co-insurance is set at an amount that could be problematic for low-income families. We understand that the 5% co-insurance on third tier non-preferred

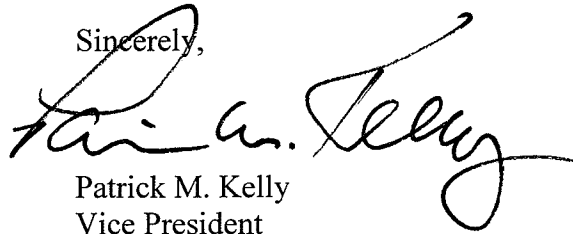
brand name drugs may soon be capped at \$20 per prescription, but this change to the co-insurance will still prove to be difficult for Medicaid patients. In fact, we believe this cost-sharing provision will ultimately do little to decrease prescription drug costs for the state, but it will essentially guarantee that Medicaid patients will not receive biologic medications. Patients should not be denied access to innovative medical therapies due to financial restrictions.

Furthermore, we question whether the state can apply the cost-sharing obligation to Medicaid beneficiaries who are at or below one hundred percent (100%) of the Federal Poverty Level (FPL). The federal Deficit Reduction Act of 2005¹ is silent on this group, and the Centers for Medicare & Medicaid Services (CMS) have indicated that they plan to provide further guidance through the rulemaking process. Specifically, CMS indicated in a letter sent to State Medicaid Directors dated June 16, 2006, that they plan to apply the limitation of section 1916² to Medicaid beneficiaries at or below 100% of the FPL.

Delivery of high quality care, including access to medically necessary medicines and treatments, should continue to be a priority of state Medicaid programs. BIO is committed to achieving that goal.

Thank you for your consideration. If you have any questions, please feel free to contact me at (202) 962-9200.

Sincerely,



Patrick M. Kelly
Vice President
State Government Relations
Biotechnology Industry Organization

¹ Pub. L. No. 109-171.

² Codified at 42 U.S.C. §1396o