



W. A. DREW EDMONDSON
ATTORNEY GENERAL OF OKLAHOMA

March 17, 2009

Abby L. Block
Director, Center for Drug and Health Plan Choice
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Director Block;

As the chief legal officers of our respective states, we submit this comment to express our support for CMS Part D Prescription Drug Utilization Management Guideline Revision #3 ("Revision #3"), relating to insurance company requirements that patients use drugs "off-label." We also recommend strengthening the Revision.

State Attorneys General have acquired substantial expertise with respect to the off-label marketing of drugs through enforcement of our consumer protection statutes. For example, in 2006 all 50 states investigated Schering-Plough's off-label marketing of the brain cancer drug Temodafor, resulting in a settlement of almost \$92 million. Similarly, in 2004 all 50 states reached a \$38 million settlement with Warner-Lambert based on its improper marketing of Neurontin. In 2005, the Attorneys General of 42 states reached a \$262 million settlement with Serono for its improper promotion of the AIDS medication Serostim, and in 2007 26 states required Purdue Pharma to pay \$19.5 million because of its off-label marketing of OxyContin. In 2008, 33 Attorneys General entered into a \$60 million settlement with Pfizer resulting in part from its promotion of Bextra and Celebrex for off-label uses.

Just as it is inappropriate for pharmaceutical companies to market drugs for off-label uses, it is equally inappropriate for health insurance companies to refuse to reimburse for physician-prescribed medications unless a patient first undergoes treatment with drugs that are off-label. Unfortunately, as you know, a number of health insurance companies which participate in Medicare Part D as "sponsors" have implemented just such a policy – with potentially serious medical consequences for patients.

This practice of requiring treatment with an off-label drug before reimbursing a patient for using a drug approved by the FDA for that specific condition subverts the legislatively mandated approval process for drug indications by substituting the judgment of health insurance companies for that of the FDA. It undermines the doctor-patient relationship by empowering health insurance companies to make broadly applicable medical decisions best left to a physician considering the needs of a specific patient. This "one-size-fits-all" insurance-company mandate is inappropriate and dangerous.

The proposed CMS Revision #3 is a welcome attempt to protect the doctor-patient relationship and to eliminate this harmful policy, and we support that effort. We are concerned, however, that the initial

clause of the proposed Revision, which prohibits sponsors from requiring off-label treatments only “[i]n the absence of widely used treatment guidelines or clinical literature”, creates a loophole that threatens to undermine the entire Revision. As a practical matter, health insurance companies already rely upon treatment guidelines or clinical literature – often of dubious validity – to justify the policy of requiring off-label treatments as a precondition to covering FDA-approved treatments. Thus, allowing health insurance companies to continue this inappropriate practice if they can find clinical literature or guidelines to support it will not address the problem. Similarly, the fact that the proposed revision requires such guidelines or clinical studies to be “widely used” offers no protection because substantial numbers of health insurance companies rely upon the same set of materials to provide a rationale for their policies. Finally, the inherently subjective nature of the term “widely used” would render the entire Revision difficult to enforce.

For these reasons, CMS should strengthen the proposed Revision #3 to prohibit sponsors from requiring the off-label use of drugs as a pre-condition for covering FDA-approved treatments prescribed by physicians. This can be accomplished by removing the first clause of the first sentence, so that Revision #3 would read as follows:

“Part D sponsors will not be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication).”

Insurance company requirements that patients utilize off-label treatments before being reimbursed for FDA-approved treatments are dangerous and should not be permitted. The same policy considerations that support a ban on off-label marketing by pharmaceutical companies support the prohibition of this insurance company practice.

Thank you for your consideration.



W. A. Drew Edmondson
Attorney General of Oklahoma



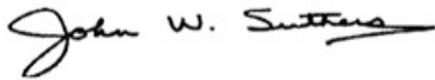
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Attorney General of Utah



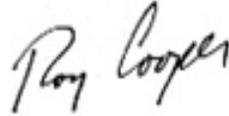
Richard Svobodny
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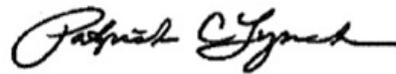
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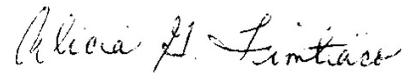


Gary King
Attorney General of New Mexico



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Attorney General of Wyoming

Abby L. Block
March 17, 2009
Page 4

A handwritten signature in cursive script that reads "Alicia G. Limtiaco".

Alicia G. Limtiaco
Attorney General of Guam