

March 6, 2006

Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: 2007 DRAFT GUIDELINES -- FORMULARIES**

Dear Centers for Medicare & Medicaid Services (CMS):

The National Community Pharmacists Association (NCPA) respectfully submits the following comments regarding the 2007 Draft Guidelines - Formularies. NCPA represents the nation's community pharmacists, including the owners of more than 24,000 pharmacies. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines.

**Specialty Pharmacy Tiers (page 6)**

NCPA supports the new guidelines established by CMS regarding pharmacy access for certain “specialty” Part D drugs. This will be a positive step forward for beneficiaries to access “specialty” pharmaceuticals at their local pharmacy.

**Six Classes of Clinical Concern (page 7)**

NCPA requests clarification on the “substantially all” exceptions. In particular, we are concerned about medications with a narrow therapeutic index (NTI). For example, in the immunosuppressant category, does CMS intend to permit formularies with generic cyclosporine and without brand forms of cyclosporine? As another example, in the anticonvulsant category, does CMS intend to permit formularies with immediate release phenytoin and without extended forms of phenytoin? Given the NTI of these agents, many prescribers are hesitant to interchange these medications for fear of adverse clinical outcomes. Often these patients have been stable with their medication regimen for a long period of time. We request additional examples of multisource brands that are contained in the “substantially all” category and ask CMS to further consider whether medications with NTI in these categories be contained on all formularies.

NCPA would like to thank CMS for the opportunity to submit these comments on behalf of community pharmacists. We look forward to continuing to work with CMS to help ensure that the Medicare Part D program is successful in 2007 and beyond. For additional information or questions about these comments, please contact Stacey Swartz, Pharm.D., Director of Management & Educational Affairs at [Stacey.swartz@ncpanet.org](mailto:Stacey.swartz@ncpanet.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'B. Roberts', with a long horizontal flourish extending to the right.

Bruce T. Roberts, R.Ph.  
Executive Vice President and CEO  
National Community Pharmacists Association