



**Association for Molecular Pathology**  
*Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology*

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May 4, 2006

Mark McClellan, Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Ave., S.W., Rm. 314G  
Washington, DC 20201

Dear Dr. McClellan:

As president of the Association for Molecular Pathology (AMP), I would like to comment on behalf of our organization's over 1400 physicians, doctoral scientists and medical technologists who perform clinical molecular diagnostic testing regarding the CMS National Correct Coding Initiative and its proposed limitation of laboratory services based on "medically unbelievable edits". We feel these proposed limits were developed without input or knowledge of our field of molecular diagnostics, and if enacted would severely compromise medical practice and patient care.

Molecular diagnostics is the newest and rapidly expanding area of laboratory medicine, offering unprecedented potential for significant improvements in personalized care, predictive testing and preventive medicine. AMP members practice their specialty in academic medical centers, independent medical laboratories, and in the *in vitro* diagnostics industry. In this capacity we are involved in every aspect of molecular diagnostic testing, administration and interpretation of molecular diagnostic tests, research and development, and education. We have provided national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing in the health care industry.

Molecular diagnostics is built on the rapidly exploding knowledge of human and microbial genomes under the impetus of the Human Genome Project and continuing advances in basic molecular biology. The remarkable complexity of these systems, which are the new "analytes" of molecular medicine, is well known to experts and the lay public alike. Only through the power of modern molecular biology can such genetic targets be assessed and understood. The sheer size of the nucleic acid sequences that must be examined necessitates the use of high-throughput, multiplexed molecular assays. The current CPT codes used in molecular diagnostics were developed and vetted with this in mind. They are primarily technique-based so as to allow for maximum flexibility in the construction of reliable test platforms. Especially for large genes with multiple mutations (e.g., the *CFTR* gene associated with cystic fibrosis), nucleic acid

amplification, probe hybridization, and sequencing steps must be used in parallel or repetitively to assure coverage of all possible target pathologies. It is for this reason that “multiplex” assays have become so predominant in our field, and will only become more so as we move into ever higher orders of complexity and encompass new technologies such as high-density microarrays. Use of only one or two molecular diagnostic codes, as defined under the current proposal, would eliminate almost all the tests we presently perform, or render them worse than useless by reducing their analytic sensitivity and clinical predictive value many-fold. This is illustrated by the many examples and scenarios being submitted to you by us and our sister organizations. Moreover, the restrictions would have the effect of interfering with the practice of medicine as currently performed by board-certified molecular pathologists and medical geneticists.

For these reasons, we strongly urge you to withdraw the proposed restrictions and open up an extended period of dialogue between CMS and the laboratory experts who understand and practice this medical specialty. Only in that way can legitimate concerns on both sides be addressed while neither compromising patient care nor hindering the continued growth and innovation of molecular diagnostics. Please contact either me or Wayne W. Grody, MD, PhD, Chair of the AMP Professional Relations Committee ([WGrody@mednet.ucla.edu](mailto:WGrody@mednet.ucla.edu)) if we can provide further information.

Sincerely,

A handwritten signature in black ink, reading "Barbara Zehnbauer". The signature is written in a cursive, flowing style.

Barbara A. Zehnbauer, PhD  
President  
[zehnbauer\\_b@wustl.edu](mailto:zehnbauer_b@wustl.edu)