

The Honorable Max Baucus
United States Senate
511 Hart Senate Office Building
Washington, D.C. 20510-2602

June 6, 2008

Dear Senator Baucus,

I am writing to express my concerns about the Centers for Medicare and Medicaid Services (CMS) recent policy changes to exclude compounded inhalation medications for Medicare beneficiaries stating that they were no longer “medically necessary”. The agency’s new policy on compounding medications and the apparent influence of the Food and Drug Administration’s (FDA) position on compounded medications had on this policy, establishes a dangerous precedent that will dramatically affect patient access to needed medications.

Compounding medicines is an essential component of the practice of pharmacy that provides physicians with the opportunity to provide patients with medicines that are prepared to the specific needs of the individual. Compounding and preparing medications pursuant to a valid prescription or physician’s drug order has always been and should continue to be a professional prerogative that is governed by the pharmacy regulatory boards within each state. Governance of the practice of pharmacy is state responsibility and should not be a matter for federal intervention. The Federal Court, based on its recent decision from *Medical Center Pharmacy vs. Gonzales*, seems to understand the issue very clearly and recognizes that medications compounded for individual patients pursuant to valid prescription are not “new drugs” and are therefore is not under the purview of the Food Drug and Cosmetic Act (FDCA) or the FDA. The broad interpretation “that all compounded drugs are unapproved and therefore illegal drugs” is a very slippery slope of regulatory intrusion on the practice of pharmacy.

We appreciate the FDA’s concern for quality, safety and efficacy of medicines. That said, pharmacists are educated and trained in the “art and science” of pharmacy which includes compounding medicines for patients who need them. Many patients have medication needs that are unmet by commercially available products. Patients often require a particular strength or dosage form of a drug that is not available on the market. Also, commercially available products may contain additives or excipients to which the patient is allergic or intolerant. To declare compounded medications illegal is to deny these patients access to needed medicines.

This new CMS policy, based on FDA’s position, may have far-reaching and serious consequences for Medicare beneficiaries who rely on nebulizer medications. Eliminating compounding will severely restrict access to these and other critical medications for Medicare beneficiaries. Moreover, the policy will limit physicians’ abilities to prescribe the medicines in the strengths, formulations, and routes of administration that are best for patient care.

I am asking that you get CMS to reconsider its position and comply with the Federal court ruling and rescind the new policy that excludes compounding. The practice of pharmacy is governed by the respective state Boards of Pharmacy through the powers granted by their legislatures. Compounding is an integral part of the practice of pharmacy and should thus fall under the governance of the profession at the state level.

Thank you for considering our comments in this matter.

Sincerely,

Eric Shields, Pharm.D.