United States Senate
WASHINGTON, DC 20510

November 15, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Acting Administrator Tavenner:

The recent outbreak of fungal meningitis has raised concerns about oversight of compounding pharmacy practices. We recognize that compounded medications play an important role in patient care, but are concerned that the practice of traditional drug compounding appears to have grown more broadly into widespread and multi-state distribution. The recent outbreak of this dangerous disease indicates a need for more information about how drug compounding practices are regulated and reimbursed at the state and federal levels.

We appreciate the swift action on the part of the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) to both identify and manage the outbreak. However, we believe this tragic incident raises additional questions regarding the coordination of payment denial for those compounding pharmacies found to be in violation of the Food, Drug and Cosmetic Act, and ask that CMS provide us with further detail on the agency's implementation of chapter 15, section 50.4.7 of the Medicare Benefit Policy Manual. As you know, this section cites explicitly those conditions that would result in a denial of Medicare payment for compounded drugs. Further, in this section, the agency requests that carriers or regional offices notify the agency when companies may be in violation of this policy.

Specifically, we would appreciate further information on the following questions:

1. What coordination does CMS have with the FDA to determine which companies have received violations for mass compounding of drugs, and how is this information given to regional offices and carriers?

2. How often has CMS stopped payment of compounded drugs in the Medicare and Medicaid programs?

3. How often have regional offices and carriers reported potential violations of compounding? How is this information shared with the FDA, and across federal health programs?

4. Within Medicare Part D, does CMS review Prescription Drug Event data to track use of compounded drugs?

5. Within the Medicaid program, what guidance has been given to State Medicaid Directors regarding the use of compounded drugs?

We would appreciate any information that you can provide on this issue, and any activities that CMS has taken with respect to compounded drugs. We look forward to working with you to better assure the safety and quality of health care delivery across our nation.

Sincerely,

Richard Blumenthal
United States Senate

Debbie Stabenow
United States Senate

Al Franken
United States Senate

Dianne Feinstein
United States Senate