Federal-State Meeting to Discuss Pharmacy Compounding

Carmen A. Catizone, MS, RPh, DPh
Executive Director
National Association of Boards of Pharmacy
Memorandum of Understanding
To qualify for the exemptions under Section 503A, a compounding pharmacy cannot ship compounded drugs interstate that exceed 5% of the total prescription drugs dispensed or distributed unless the state in which it is located has signed a memorandum of understanding (MOU) with Food and Drug Administration (FDA).
The MOU must address the distribution of inordinate amounts of compounded drug products interstate and provide for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside the state.
Guidance for Industry

MOU – 1999

In consultation with the NABP, the agency is currently developing a draft standard MOU on pharmacy compounding that would establish a cooperative program between FDA and state agencies that choose to enter into the MOU, regarding the regulation of interstate distribution of compounded drug products.
MOU – 1999

• The Guide listed examples of activities that the FDA believed raised concerns and would be considered in determining whether to bring an enforcement action.

• The Guide further warned that pharmacies could not dispense drugs to third parties for resale to individual patients without losing their status as retail entities.
Considerations and Substance of the MOU

• Define “inordinate amount”
• Measurable metrics to define and determine “5%”
• Not a bypass for “office use” or “stock” compounding
• Communication and enforcement collaboration with the states