Food and Drug Administration
Fifty State Meeting

National Association of Boards of Pharmacy
Carmen A. Catizone, Executive Director
Outsourcing Facilities

• Experiences to Date
  – VAWD
  – VPP

• Classification and Licensure

• 503A vs 503B
  – Inspections
  – Training

• Additional Issues
Outsourcing Facilities

• Experiences to Date
Classification and Licensure

• Recommendation to license as separate entities
  – Current state classifications
  – Limiting factors on State actions
• Conflicts between State laws/regulations
• Model Act
• Interim strategies
To Patient or Not to Patient

- Inspections
  - Frequency
  - Standards
  - cGMPs

- Interpretation and legal standing of actions