SIMPLIFIED ILLUSTRATION OF PRESCRIPTION STIMULANT AVAILABILITY

MEDICAL NEED

FDA REGULATION

DEA MONITORING

MANUFACTURERS
DEVELOP/PRODUCE
MEDICATIONS

WHOLESALE
DISTRIBUTORS
SHIP MEDICATIONS

PHARMACISTS/
PHARMACIES
DISPENSE
MEDICATIONS

PERSON BUYS
MEDICATION
FACTORS THAT AFFECT PRESCRIPTION STIMULANT AVAILABILITY

- **Medical Need**
  - Set and Allocate Quotas
  - DEA Monitoring
  - Record-keeping Requirement
  - Product Movement Limitation

- **FDA Regulation**
  - FDA Facility Inspection
  - FDA Provides Annual Estimates of Need to DEA
  - Review Medication Formulation
  - Review Manufacturer Producing Formulations
  - Track & Trace Requirements
  - Approve Medication
  - Approve Manufacturers

- **Economic Analysis**
  - Source Raw Materials and Chemicals
  - Apply for DEA Quota
  - Manufacture Medication
  - Check and Maintain Stock
  - Determine Order Type for Processing
  - Ship Only If Under DEA Quota

- **Manufacturers Develop/Produce Medications**
  - Review Diversion Monitoring List and Report to DEA
  - Check Product Movement Limitation for Each Pharmacy and Product
  - Verify DEA Paperwork
  - Add Track and Trace Information
  - Pack and Ship Medication

- **Wholesale Distributors Ship Medications**
  - Report to DEA
  - Report to State
  - Ship Only If Order Does Not Exceed Limits for Each Pharmacy and Each Product

- **Pharmacists/Pharmacies Dispense Medications**
  - Check for Allergies and Interactions
  - Verify Legitimacy and Clinical Appropriateness of Prescription
  - Check and Maintain Stock
  - Pack and Ship Medication

- **Person Buys Medication**
  - Submit to Insurance or Determine Patient Affordability
  - Disperse Only After Confirming Patient Affordability
  - Process After Checking Prescription History in Prescription Drug Monitoring Program
  - Process Only If Clinically Appropriate and Legitimate Prescriptions