



# To speak or not to speak...

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# Objectives

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- At the conclusion of the program the participant:
  - will understand the responsibilities of a pharmacist upon receipt of notice of a Board inspection/investigation.
  - will understand the responsibilities of a pharmacy owner upon receipt of notice of a Board inspection/investigation.



# Objectives (continued)

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- will be prepared to respond to a notice of inspection/investigation by a Board inspector.
- will understand the necessity for adequate preparation for visits by a Board inspector.



# Preparation for Inspection

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- Know your inspector.
- Review the previous inspection form.
- Develop a plan to improve.
- Document adherence to plan.
- Assess the effectiveness of the plan.
- Involve entire pharmacy staff.



# Inspection v. Investigation

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- Inspections
  - quantitatively and qualitatively different.
  - routine in nature.
  - educational emphasis in most cases.
  - opportunity to dialogue.



# Inspection v. Investigation

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- Investigation

- What is the genesis?
- Who is the complainant?
- What has the complainant alleged?
- Can a copy of the complaint be obtained?
- Notification of liability insurance carrier.
- Notification of management.
- What evidence is already available?



# Inspection v. Investigation

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- Administrative.
- Civil.
- Criminal.
- Board or multi-jurisdictional.
- Personal license, business license, both.
- Colleague.



# Authority

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- Compliance with procedure.
- Know the Board members.
- Know the philosophy of the Board.
- What are the Board's powers.
- What are the disciplinary guidelines.
- What has the Board done in the past.



# Gathering Information – Search Warrants

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- Warrantless Searches
  - Pervasively Regulated Industry
  - Explicit Statutory Authority
    - Essential to furtherance of important government objective
    - Scope limited by statute to specific purposes, places and times
  - Implied Consent (by virtue of licensure)



# Gathering Information – Search Warrants

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- Warrantless Searches - Consent
  - Knowing and voluntary
  - “Do I have a choice?” - mere acquiescence to authority is not consent
    - *US v Anile*, 352 F Supp 14 (W.Va. 1973)
  - “Sign consent or face criminal penalties” - coerced consent
    - *US v. Enserro*, 401 F Supp 460 (SDNY 1975)



# Gathering Information

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- Administrative Inspection Warrant
  - Application without probable cause
  - Less specific in description of scope
  - Forcible Entry Not Permitted
  - “Regular Business Hours”
  - FDA tool for inspecting compounding pharmacies
    - *Wedgewood Pharmacy*, 270 F Supp 2d 525 (D.N.J. 2003)



# Gathering Information

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- Search Warrants - Criminal
  - Probable Cause
  - Specific description of subject matter and location
  - Forced entry permitted
  - No advance notice
  - Can be served at anytime



# Gathering Information – Subpoena *duces tecum*

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- Less stringent standards for issuance
  - Comply, object or move to quash in timely fashion
  - If you comply, define scope and limit your response
  - HIPAA/State Law Privacy Considerations
    - Obtain “satisfactory assurances” or provide notice?
    - Be mindful of “minimum necessary”?



# Gathering Information – Subpoena *duces tecum*

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- Requires response
  - Preserve all potential statutory and common law privileges and other objections
  - Assume that there will be follow-up
    - Prepare employees for inspection
    - Advise employees of rights
    - Consider internal investigation

# Gathering Information – Interviews



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- Primary Objective of Agents
- Purely voluntary and completely unfair
  - Options include consent, decline or postpone
  - If you consent
    - Do not lie
    - Do not sign statement
  - Consent can be withdrawn at anytime



# Gathering Information – Interviews

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- Statements cannot be coerced
  - Warrant does not give authority to interview
  - Subpoena does not give authority
  - Nothing is “off the record”
  - Agents have no authority to grant immunity or leniency



# Gathering Information – Interviews

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- Consequences of talking
  - Incriminating statements will be used against you
  - False statements subject you to criminal penalties
    - 18 USC § 1001
    - Obstruction of Justice – state or federal
  - No win situation



# Investigations

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- Be prepared.



# Preparing for an Investigation

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- Must have a game plan – in advance - that covers all bases
- Develop policies and educate employees
- Identify response teams with specific responsibilities



# Preparing for an Investigation

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- Set up compliance program and adhere to it
  - Ongoing
- Have document retention and destruction policy and adhere to it
  - Protect and segregate privileged documents



# Preparing for an Investigation

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- Once “notice” of investigation is received:
  - Directives concerning documents should be made only by predetermined individuals, and no others
  - Counsel should be engaged
  - Employees should be notified
  - All communications should be directed to counsel.



# Preparing for an Investigation

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- Identify types and scope of permitted inspections
  - Warrant, Administrative Warrant, and Warrantless
  - Each requires different approach
  - Review applicable laws and determine approach for each type of inspection



# Preparing for an Investigation

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- Policies – address each type of investigation
  - Scope of warrant
    - Required for DEA/FDA accountability audits
  - If warrantless, do not consent
    - Resist or allow inspection under protest
  - If warrant presented
    - Do not resist or obstruct
    - Do not consent to expansion of scope



# Preparing for an Investigation

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- Agents at the door
  - Examine credentials
  - Note name, agency, badge number
  - If items seized
    - Make copies of records
    - Obtain copy of warrant as receipt
  - Take notes of agent's activities / comments
  - Do not sign anything other than receipt for samples or agent's report



# Preparing for an Investigation

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- Agents at the door
  - If samples are taken, you should also preserve samples
  - Do not allow photographs unless specifically permitted by statute or warrant
  - **DO NOT CONSENT TO INTERVIEWS**
  - Contact legal counsel as soon as practicable



# Post investigation procedures

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- Statutory response times.
- Don't call attorney on last day.
- Extensions may not always be granted.
- Limit responses to minimum needed to preserve rights.
- Selection of hearing type: formal, informal, settlement conference, ADR.



# Post-investigation procedures

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- Stipulation of facts
  - Jurisdiction of constitutional issues.
- Witnesses.
- Experts.
- Considerations of effect on workplace
  - Back-up and additional servers.
  - Selection of battles.
- Always think of appeal.



# Questions

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- True or False

- A pharmacist should have liability insurance separate from that of the business.
- A pharmacist may rely upon the failure of the Board to follow principles of procedural due process in the investigation of an administrative action.



# Questions

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- A pharmacy must prepare for the eventual inspection of its premises.
- A pharmacy and pharmacist may use the newsletter as a guide of the current interests of the inspectors of the Board.
- A pharmacy and pharmacist should not be concerned with collateral consequences of a Board action as they may interpose the defense of collateral estoppel and res judicata.



# Contact Information

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