

Overview of the process:
From inspection, investigation to hearing

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The presentation was created by Darrell Contreras, Esq. The following slides are provided for your information and are not intended to provide legal advice. Please consult your legal counsel for official legal advice.

Darrell Contreras Background

- *Over 15 years of legal and compliance experience*
- *Knowledgeable about the current and proposed laws and regulations*
- *Trained by former law enforcement and regulators*
- *Expertise in.....*
 - ❖ *translating legal and regulatory requirements into practice*
 - ❖ *identifying risk areas and mitigating that risk*
 - ❖ *auditing for compliance with regulations and sampling methodologies*

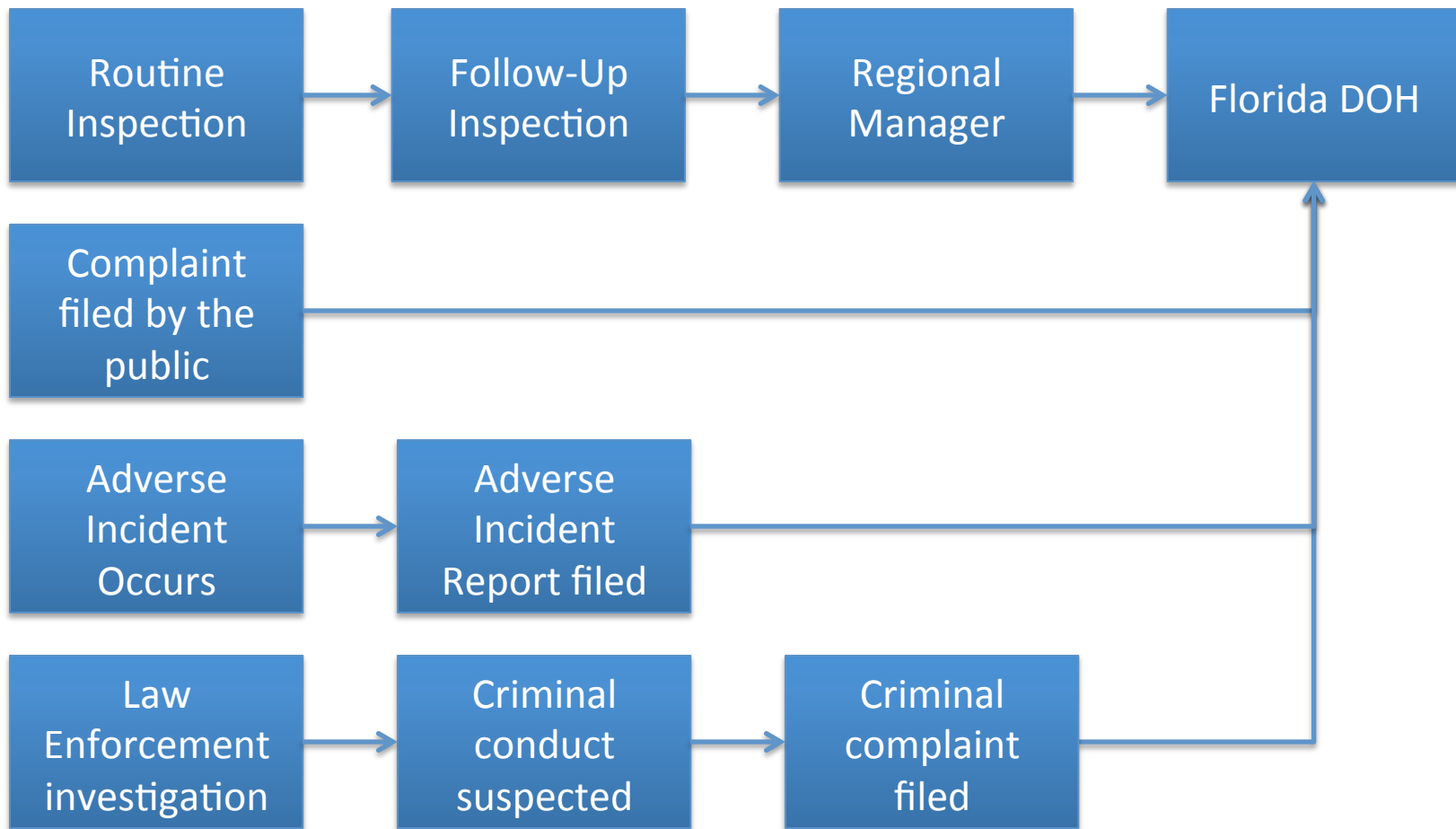
Objectives

- Identify how the Board of Medicine begins an investigation
- Understand the investigation process
- How to respond to an investigation

How Do Investigations Begin?

- Florida Department of Health (DOH) investigates complaints
- Sources for complaints:
 - ❖ Inspection – Annual DOH pain clinic inspections
 - ❖ Public complaints – patient complaints or reports from other sources, e.g., pharmacies
 - ❖ Reporting – Reporting of adverse events (458.351 Florida Statutes) to the DOH
 - ❖ Law enforcement – As part of a criminal investigation, e.g., DEA, Sheriff's Department

How Do Investigations Begin?



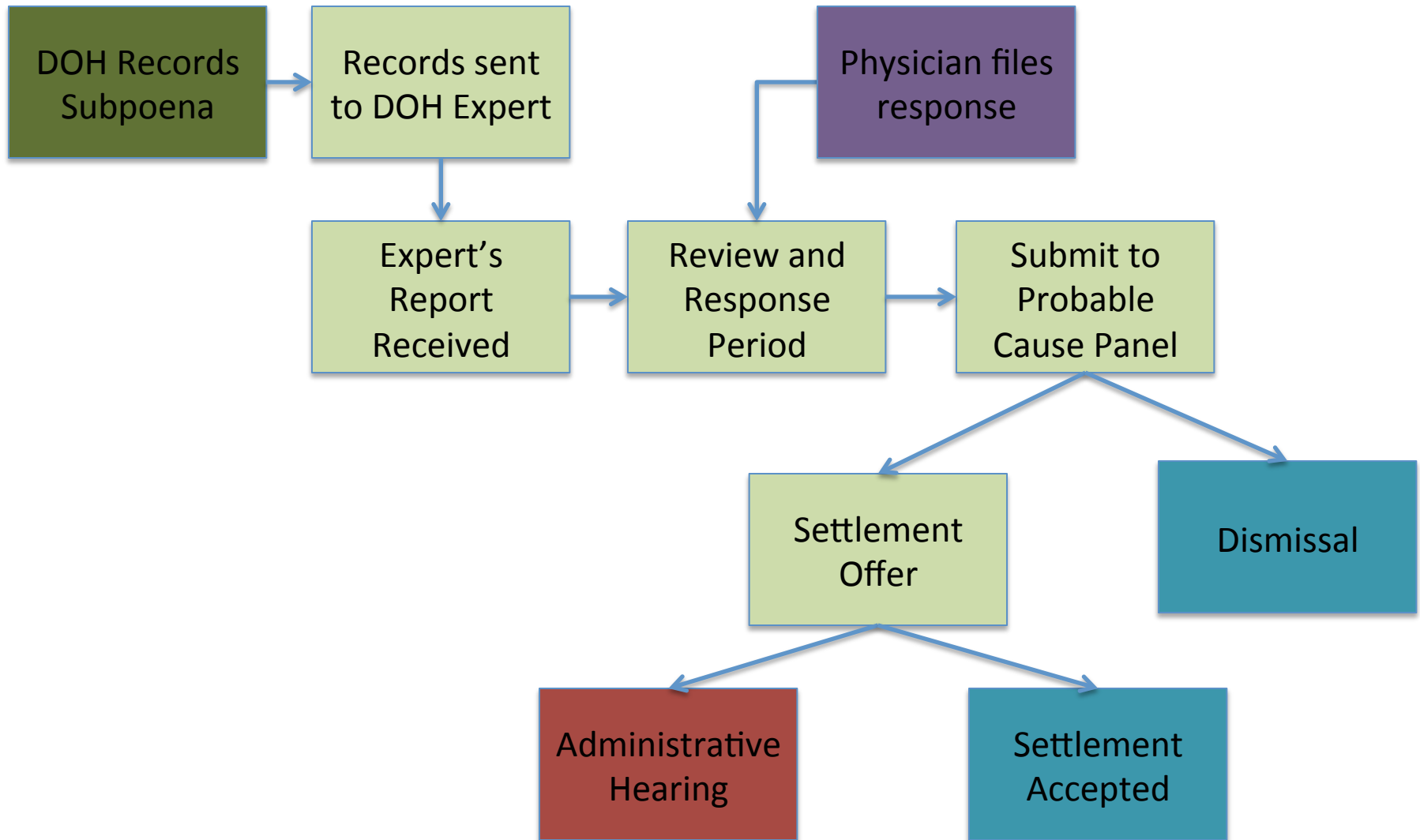
Investigations from Inspections

- Result from a failure to implement corrective action during initial inspection
- Reports are filed locally
 - ❖ A letter will be sent to the physician offering an opportunity to respond
 - ❖ The response, plus the original report will be forwarded to the State
 - ❖ Unlikely to prevent forwarding to the State

DOH has the complaint, now what?

- DOH determines whether it becomes a Board of Medicine review. The steps are:
 1. Record request (could also happen at the local level)
 2. Records are reviewed by an expert
 3. Opportunity to review the expert's report
 4. Opportunity to respond to the expert's report
 5. Submission to Probable Cause panel with recommendation from DOH to pursue or dismiss
 6. Probable Cause Panel result options:
 - a) Dismissal
 - b) Settlement offer
 7. Administrative Hearing if disagree with Settlement offer

How Do Investigations Begin?



What should I do?

- Step 1: Hire an attorney
 - ❖ Expertise in administrative proceedings
 - ❖ Hire as soon as you receive notice of record review
 - Ensure subpoena is valid
 - Facilitate the review
 - Identify opportunities to address concerns
 - Compile favorable evidence

What should I do? (continued)

- Step 2: Provide the requested records
 - ❖ Make sure **ALL** documents are included in the submission to DOH
 - ❖ Make sure copies are legible, e.g., drivers license copies, prescriptions
 - ❖ Keep complete copies of the records submitted
 - ❖ Have attorney communicate timelines with the DOH

What should I do? (continued)

- Step 3: Review the submitted records
 - ❖ Take notes – Is your documentation complete? Are there vulnerabilities?
 - ❖ Be objective in your review
 - ❖ Note the dates of the requested records and what laws and standards were in place AT THAT TIME:
 - Pain Clinic laws went into effect July 1, 2011
 - E-FORCSE available October/November 2011
 - What were typical prescriptions during that time?
 - ❖ **Be ready for the expert's response to be inflammatory!**

What should I do? (continued)

- Step 4: Respond to the Expert's Report
 - ❖ Rebut the expert's areas of concern (see next slide)
 - ❖ Use your documentation to rebut any presumptions, perceptions or suspicions
 - ❖ Research the expert
 - Malpractice settlements
 - Adverse administrative actions
 - ❖ You may need a medical or regulatory expert

Expert Reports

- Typical Areas of Concern (not in order):
 - ❖ Prescription quantity/dosage
 - ❖ Documentation of physical examination
 - ❖ Combination of medications
 - ❖ Referrals for or consideration of other treatments
 - ❖ Follow-up on referrals for other treatments
 - ❖ Plan of care for continued controlled substance therapy
 - ❖ Urine drug screening/testing
 - ❖ E-FORCSE check

Expert Reports

- Presumptions, Perceptions and Suspicions:
 - ❖ Patients from closed clinics are drug seekers
 - ❖ Clinics that prescribe without interventions are not providing proper care
 - ❖ Cash only clinics do not provide proper referrals

What should I do? (continued)

- Step 5: Be Involved and **AGGRESSIVE!**
 - ❖ This **WILL NOT** go away by itself
 - ❖ Silence or missed deadlines = guilt

Protect Yourself Moving Forward

- Always document your physical examination
- Document the patient's current condition, including changes
 - ❖ no change is a current condition
- Document patient follow-up on past recommendations/referrals
- **Make sure there is a reason documented for your prescription**

Questions?

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