

# New York State



# Office of Professional Discipline

# Regional Offices

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# Buffalo Investigators

- Supervising Investigator Gail Swanson
  - Senior Investigator Denise Kleinsmith
  - Senior Investigator Tony Mastantuono
  - Senior Investigator Michael Lenig
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- 65yrs+ collective investigative experience

# Our Mission

- An agency within the NYS Education Department chartered to protect the public by fostering high standards of professional licensure, practice and discipline.
- Responsible for investigating and prosecuting -
  - Allegations of professional misconduct/negligence
  - Allegations of practicing w/o proper licensure
  - Conduct investigations into moral characters and fitness under title VIII of the Education Law
- OPD Goal is to produce complete, objective, and factual investigative reports.

# Laws, Rules and Regulations

- Professional misconduct determined by violations of:
  - Education Law § 130 & 139, 6806, 6808, 6809, 6811
  - Commissioner Regulations parts 52 & 64
  - Regents Rule part 29

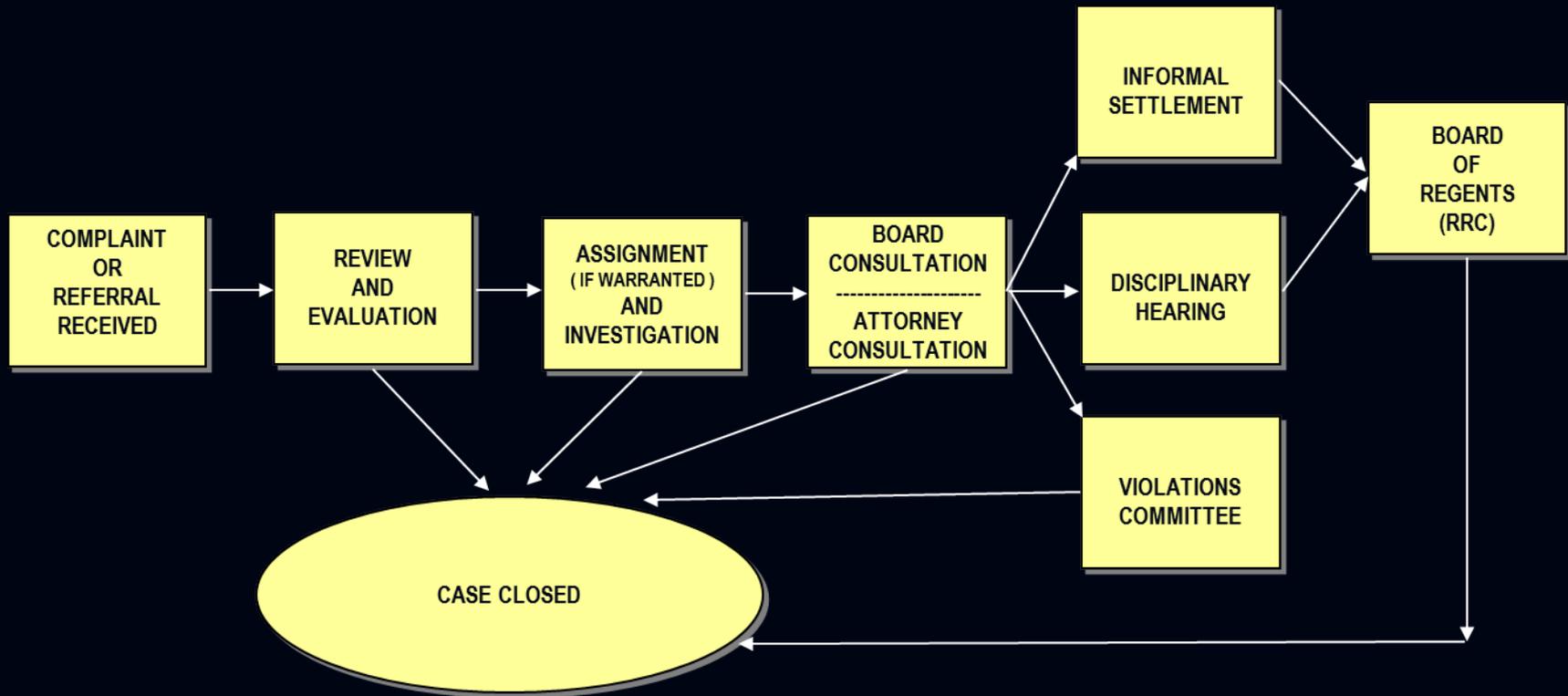
# Knowledge is key

- Education law §6811: It shall be a class A misdemeanor for:
  - Any person knowingly or intentionally to prevent or refuse to permit any board member or department representative to enter a pharmacy or any other establishment for the purpose of lawful inspection;
  - Any person to manufacture, sell, deliver for sale, hold for sale or offer for sale of any drug, device or cosmetic that is adulterated or misbranded

# Sources of Complaints and Referrals

- Individual complainants or patients
- Local/Federal Law Enforcement Agencies
- Media reports
- Internally generated investigations

# Investigative Process



# Inspections - what to expect

- We review history first and foremost
  - Past inspections/violations/disciplinary actions etc.,
- We will observe first before contact - includes exterior
  - Verify licensure displayed and current
  - Proper sanitation and supervision
- We WILL identify ourselves with badge and credentials
  - Attempt to be minimally intrusive
  - Checking everything to include temperature of facility

# Inspections - what to expect

- If an investigator notices something but is unsure of compliance/regulation – they will
  - Consult with Regional Pharmacy Coordinator
  - Consult with Pharmacy Board
  - Review Continuity Book
  - Relay findings back to pharmacist
- When a new regulation/statute or policy is approved OPD Investigators are oriented on enforcement procedures by the Regional Pharmacy Coordinator.

# Inspections - what to expect

- Investigators performance to ensure consistency in the enforcement process is reviewed by upper management
  - Investigators - Investigate
  - NYS appointed Pharmacy Board Members and OPD Prosecutors enforce the standards
- Inspections are also used as educational and learning interactions with pharmacy staff.

# Common violations during inspections

- Drug stock not current/misbranded/expired
- Improper ratio of pharmacist: unlicensed persons
- Not offering counseling/not documenting refusals
- Unsanitary conditions (garbage/dust/dirt)
- Pills on floor/in drawers
- Automated dispensing machines
  - Cell labeling – each should indicate Drug/Strength/Lot/Exp etc,
- Unable to locate requested documents
- Licenses/registrations not displayed

# Investigation Process

## What to expect

- We will request documents pertaining to allegation
  - prescription/PT profile/daily ledger, etc.,
- We may conduct an inspection
- We will interview personnel
- You may be asked to describe aspects of your profession to identify if you understand the requirements. (i.e. dispensing process/quality review/counseling/etc.,

# Investigations - what to expect

- If investigation goes to hearing – the investigator may be part of the hearing process.
  - The investigator is part of the process and provides briefings to board members on violations and investigative findings.
  - If investigator made error in enforcement unlikely to have hearing.
  - No reimbursement to pharmacist for attorney fees
    - If enforcement error – would be identified early enough.

# Investigations - what to expect

- Investigation goes to hearing only if professional misconduct has been identified and no settlement is reached between OPD and Pharmacist.
  - Pharmacist is able to settle proposed disciplinary action with NYS prior to any official administrative hearing.

# Situational Awareness

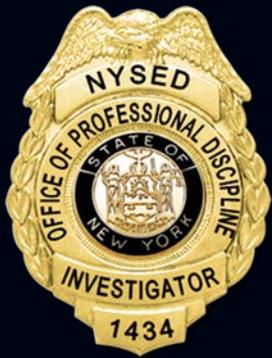
- Be vigilant in protecting your pharmacy license.
  - Avoid criminal convictions (DWI, diversion, use, etc).
  - Infractions/Felonies/Misdemeanors etc.,
- Don't become complacent in routine pharmacy activities.
  - Don't ignore things like sanitation, outdated/misbranded drugs, adequate and functional facilities and equipment.
  - If problems arise address them w/your Supervising Pharmacist or District Manager.

# Situational Awareness (cont.)

- Be aware of laws, rules, and regulations governing profession. Attention to detail on record keeping.
- Maintain oversight of unlicensed persons assisting. Remember, if an unlicensed person made the error, you are still responsible and accountable.
- Don't become complacent in routine activities.
  - Don't ignore things like sanitation, outdated/misbranded drugs, adequate and functional facilities and equipment.

# Penalties

- Reprimand – Corrective Action Letter – Admin Warning
- Monetary Fines: \$250 - \$10,000
- Probation: 1 Month – 2 Years
- Mandatory Education/Testing/Reports
- Suspension: 1 Month – 5+ years – Until Fit
- Revocation or Voluntary Surrender



# Investigation Summaries

**SUBJECT:** SP and Pharmacy (SP is Owner of Pharmacy) / 3403936;3403934

**Status:** At Violations Committee for finalization:

**Summary:** Routine inspection – Rph on site; SP, also owner not present. Violations found: Outdated stock – Expired compounding material - some displayed expirations dating back to 2012. Expired over the Counters (OTC) being sold at discounted prices. One (1) container of suspected Boric Acid Dust found on shelf with no top and no label.

**Disciplinary Action:** Recommendation pharmacy receive VC \$1100 and Supervising Pharmacist receive VC \$800.



# Investigation Summaries

**SUBJECT:** Pharmacist (SP) and Corporation

**Summary:** Routine inspection – Rph on site; SP on LOA (4mo).

**Violations:** Expired SP Registration; “Acting” SP - identified himself as a “floater” had no registration displayed & unable to provide - stated unaware of requirements to produce and display. Expired medications not disposed within required timeframe. Multiple pills on floor throughout pharmacy; sink inaccessible due to multiple trash bags. Acting SP unable to locate inspectable documents.

**Disciplinary Action:** Pharmacy received VC \$550 and Supervising Pharmacist received CAR.



# Investigation Summaries

**SUBJECT:** Pharmacist (SP) and Corporation / 3403017; 3403016

**Status:** At VC for Company adjudication– SP received VC \$550.

**Summary:** Routine inspection – Rph on site; SP not present.

**Violations:** Misbranded Medication – no lot numbers or expiration dates. Medication labeled “Retrieved from Automation” was also found on the shelf. Medication (10+) pills found on floor, in container drawers and in Script Pro dispensing machine. General housekeeping - floors soiled container drawers dirty.

Pharmacist questioned regarding medication labeled “Retrieved from Automation.” stated medication was to be destroyed - could not provide explanation why on shelf.

**Disciplinary Action:** Recommended pharmacy receive VC \$1500. (pharmacy has 3 prior fines).



# Investigation Summaries

**SUBJECT:** Pharmacist (SP)

**Summary:** Complaint initiated Investigation – SP dispensed wrong dose of Zantac to infant child born premature, DX w/ acid reflux. Error equated to 15x originally intended dose. Rx was filled by Technician w/20yrs experience -- read script wrong. Liquids normally prescribed written in milliliters. this Rx was written in “milligrams.”

**Contributing factors** – SP experience –only RPh 6mo before becoming SP; New Pharmacy Metrics (only six (6) baskets waiting for verification @ any time and 15 min verifications after entry); Company policies severely detrimental to operation.

**Disciplinary Action:** VC \$500.

**Additional information:** Media attention – SP could not get job in local area - moved out of state.



# Investigation Summaries

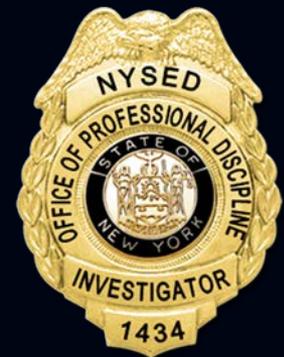
**SUBJECT:** Pharmacist (SP)

**Summary:** Complaint initiated Investigation – Led to inspection and Violations.

SP dispensed incorrect dose of Combivent Respimat Inhaler. Rx was e-scribed from physician, SP contacted MD inquiring on dosage – told correct and therefore dispensed. Documented accordingly. Investigation led to inspection – second case initiated.

**Violations:** Restocked medications did not contain dates, making it impossible to identify if current. Multiple pills found on floor throughout pharmacy, even in the consultation room. **36+ pills were found.**

**Disciplinary Action:** Initial complaint resulted in No violation for SP – documentation proved no misconduct. On subsequent inspection case - SP received a CAR and Corporation rec'd VC \$500.



# Investigation Summaries

**SUBJECT:** Pharmacist / 3502742

**Status:** At VC for adjudication.

**Summary:** Complaint initiated investigation - diverted controlled substance and usage of the controlled substance in work place.

SUBJECT was found having difficulty standing, speaking and was not responding to co-workers. A code was initiated - SUBJECT was taken to the ER. A co-worker assisting SUBJECT found used syringes on SUBJECT's person.

SUBJECT admitted taking waste from the preparation of a Sufentanil I.V. drip and injecting it into their body prior to leaving work, hoping it would help them sleep.

**Disciplinary Action:** Recommended suspension until fit; 2yr probation; \$500 fine.



# WEBSITE OVERVIEW