COMPLIANCE SECTION
CONSUMER SAFETY BRANCH

Drugs and Medical Devices



FY26 ANNUAL ANALYSIS
FINAL ENFORCEMENT ACTIONS

Pursuant to 25 Texas Administrative Code 1.553(a)(1)(2)

DMD Policies & Procedure Requirements

Drugs and Medical Devices (DMD) ensures drug manufacturers and distributors comply with minimum licensing standards to protect the health and safety of Texans.

DMD inspect prescription and over-the-counter (OTC) drug manufacturers and distributors to make sure they meet these standards. When voluntary compliance with the licensing standards cannot be achieved, DMD recommend regulatory actions.

DMD also provide technical assistance to licensees, answer questions from consumers and investigate complaints involving possible violations of the state requirements for drug manufacturers and distributors.

Prescription drug distributors are required to establish, maintain and adhere to all written policies and procedures required in 21 CFR, Part 205 - Section 205.50(g). Among these are policies and procedures for the receipt, security, storage, recall, inventory (including correcting all errors and inaccuracies), and distribution of prescription drugs (e.g., stock rotation; identifying, recording, and reporting losses or thefts; and disaster preparedness).

Drug Manufacturers and Distributors Defined

Drug Manufacturers:

A person who manufactures, prepares, propagates, compounds, processes, packages or repackages drugs, or a person who changes the container, wrapper or labeling of any drug package. A person licensed or approved by the United States Food and Drug Administration to engage in the manufacture of drugs consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidance implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293). The term does not include a pharmacist engaged in compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Occupations Code, §562.154.

Drug Distributors:

A person engaged in the wholesale distribution of prescription drugs, including, but not limited to, a distributor, wholesaler, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized distributor of record, independent wholesale drug trader, specialty wholesale distributor, third-party logistics provider, retail pharmacy that conducts wholesale distribution, and a pharmacy warehouse that conducts wholesale distribution.

Drugs and Medical Devices License Types

2501 - Prescription Drugs

2502 - Nonprescription Drugs

2503 - Devices

2504 - Multiple Products

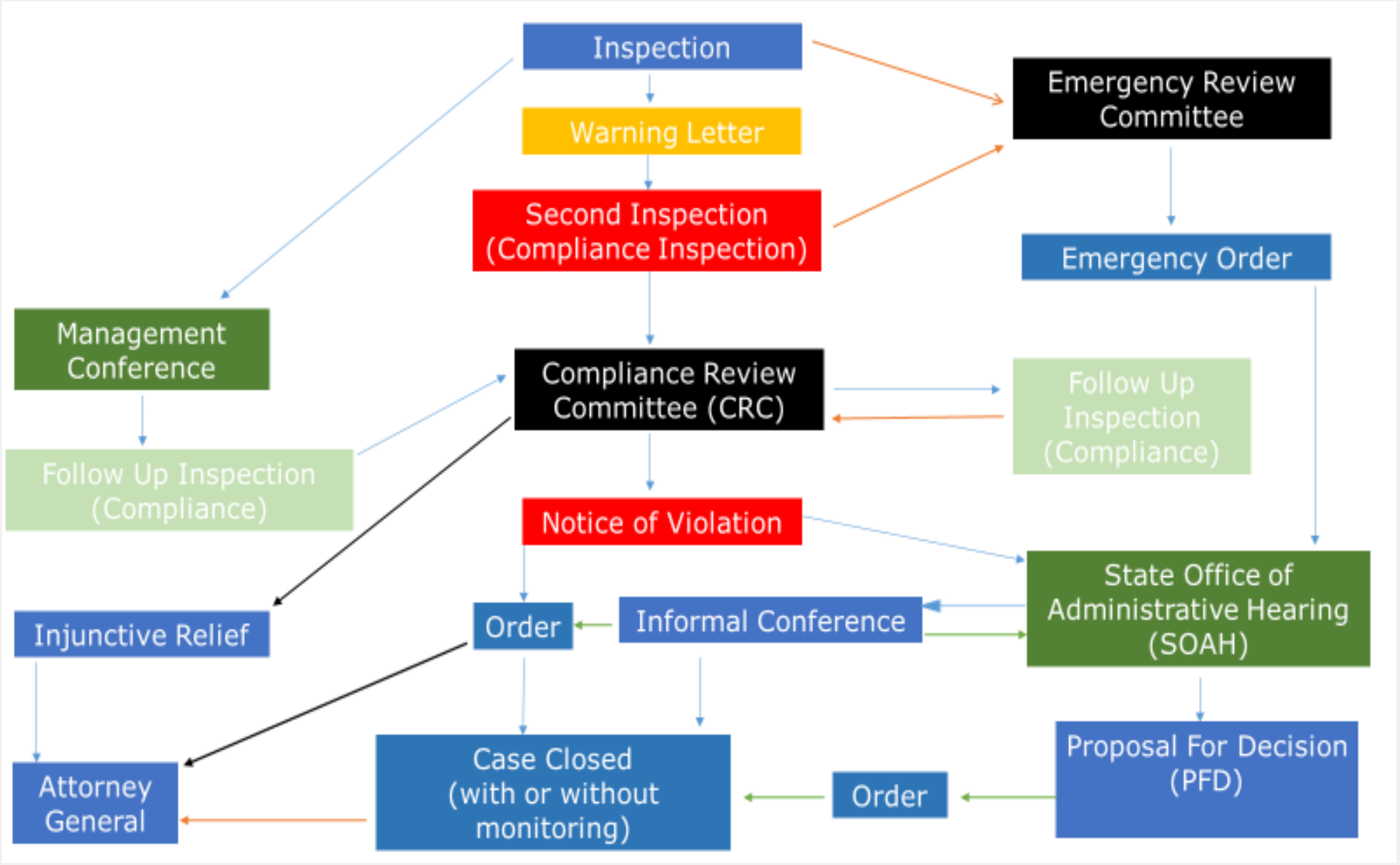
2506 - Tanning Facility

2510 - Pseudoephedrine

2511 - Bloodborne Pathogens

2520 - Owners

Drugs and Medical Devices Compliance Flowchart



TEXAS Health and Human Services

Texas Department of State Health Services

Cases referred to Compliance

- Sixteen (16) cases were referred in total:
- All sixteen (16) cases were triaged through Compliance Review Committee (CRC)

CRC	16
Total	**16**

Outcomes

After triage at CRC:

- Fourteen (14) Notice of Violation (NOV) letters were cleared to be issued
- Two (2) Attorney General (AG) referrals for Injunctive Relief were cleared to be issued

Informal Conference (IC)

Seven (7) cases were heard at an IC:

- Seven (7) cases were settled after the IC with an Agreement between the Department and the Respondent

State Office of Administrative Hearings (SOAH)

Compliance referred one (1) cases to SOAH, at the request of the Respondent pursuant to HSC Sec. 432.022 and Chapter 2001, Government Code.

SOAH REFERRAL	1

- All Respondents were offered the opportunity to have their case(s) presented before an Administrative Law Judge.

Orders & Agreements Processed

- Nine (9) Agreed Order/ Acceptance Order (AO)
  - An Agreed Order is issued after an informal conference to document and memorialize the settlement agreement reached between a Respondent and the Department.
  - An Acceptance Order is issued when a Respondent accepts the proposed disciplinary action in the Department's Notice.

Cases Closed With or Without Monitoring

Cases that have a finalized Order or an Agreement are either:

- Closed with monitoring
  - Terms and conditions to be met are still pending
- Closed without monitoring
  - All terms and conditions are met

Cases closed with or without monitoring cont.

Cases closed with monitoring : 7

Cases closed without monitoring: 20

Cases withdrawn: 1

Total Penalty Amount Proposed/ Assessed

$215,000.00

TEXAS
Health and Human Services

Texas Department of State Health Services

Total Penalty Amount Remitted/ Collected

$14,185.93

TEXAS
Health and Human Services

Texas Department of State Health Services

Thank You