

COMPLIANCE SECTION

CONSUMER SAFETY BRANCH



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Drugs and Medical Devices



FY-24 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:

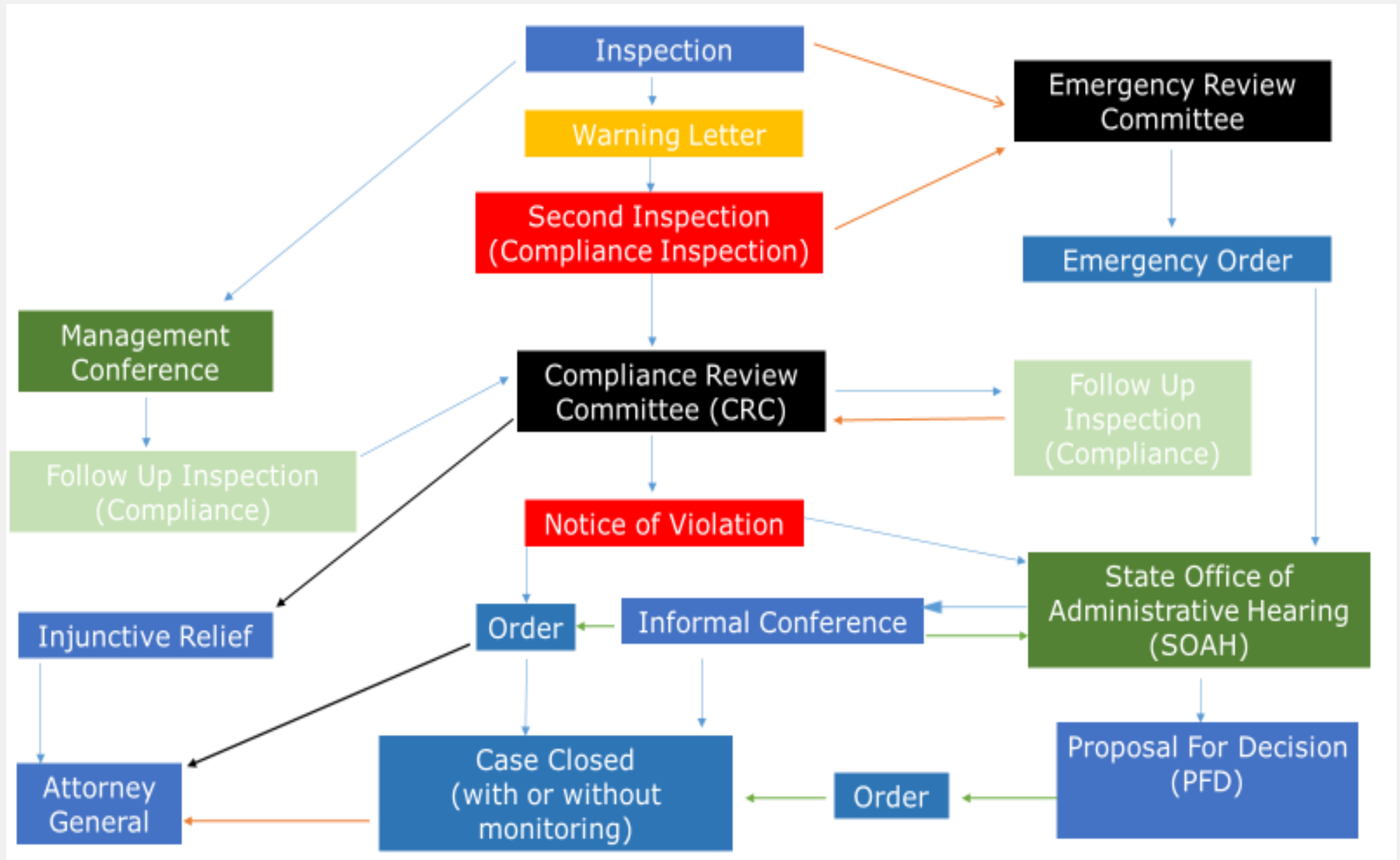
A person engaged in the wholesale distribution of prescription drugs, including, but not limited to, a distributor, wholesaler, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized 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



Cases referred to Compliance

Two (2) cases were referred in total

CRC	2
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Outcomes

After triage at CRC:

- Two (2) Notice of Violation (NOV) letters were cleared to be issued
- One (1) case was referred to the Attorney General



Informal Conference (IC)

One (1) case was held at an IC



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State Office of Administrative Hearings (SOAH)

- ❖ One (1) cases was referred to SOAH.
- ❖ All Respondents were offered the opportunity to have their case(s) presented before an Administrative Law Judge.

SOAH REFERRAL	1
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Orders

Two (2) Orders Processed

Acceptance - 1

Agreed - 1



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Attorney General (AG) Referrals

- One (1) case was referred to the AG for further administrative and/or judicial remedy because the Respondent failed to and/or refuse to comply with a final order.



FY24 Cases Closed With or Without Monitoring

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

- Two (2) cases were closed with monitoring
 - Terms and conditions to be met are still pending
- Five (5) cases were closed without monitoring
 - All terms and conditions are met

Grand Total Penalty Amount Assessed

\$11,250.00



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For more information regarding Compliance Consumer Safety policies and protocols, please click on the link below:

[Compliance Section - Consumer Safety Branch Procedure Manual.pdf - All Documents \(sharepoint.com\)](#)



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Thank You



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