

COMPLIANCE SECTION

CONSUMER SAFETY BRANCH



TEXAS
Health and Human
Services

Texas Department of State
Health Services

PRESCRIPTION DRUG PRICE DISCLOSURE



FY25 ANNUAL ANALYSIS FINAL ENFORCEMENT ACTIONS

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

Overview

The Prescription Drug Price Disclosure (PDPD) Program (formerly called Drug Cost Transparency Program) moved from HHSC to Texas Department of State Health Services (DSHS) on Sept. 1, 2021. Texas Health and Safety Code Chapter 441 requires pharmaceutical drug manufacturers to report their current wholesale acquisition cost (WAC) of U.S. Food and Drug Administration-approved drugs sold in or into Texas.

Pharmaceutical drug manufacturers also are required to separately report specific information related to WAC increases.

Disciplinary actions are taken by DSHS on violators of PDPD's governing law and rules. The severity of the disciplinary actions taken hinge on the magnitude of the significant public health concern associated with the violation, examples include but are not limited to the nature of the violation, the history of previous violations, efforts made to correct the violation, harm to the public, likelihood of a repeat violation, and other matters related to each case as justice may require. These actions are taken to protect and promote the health, safety and general well-being of the citizens of Texas.

Overview continued

Additional information are assessable via the links below:

<https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/frequently-asked-questions>

<https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview>



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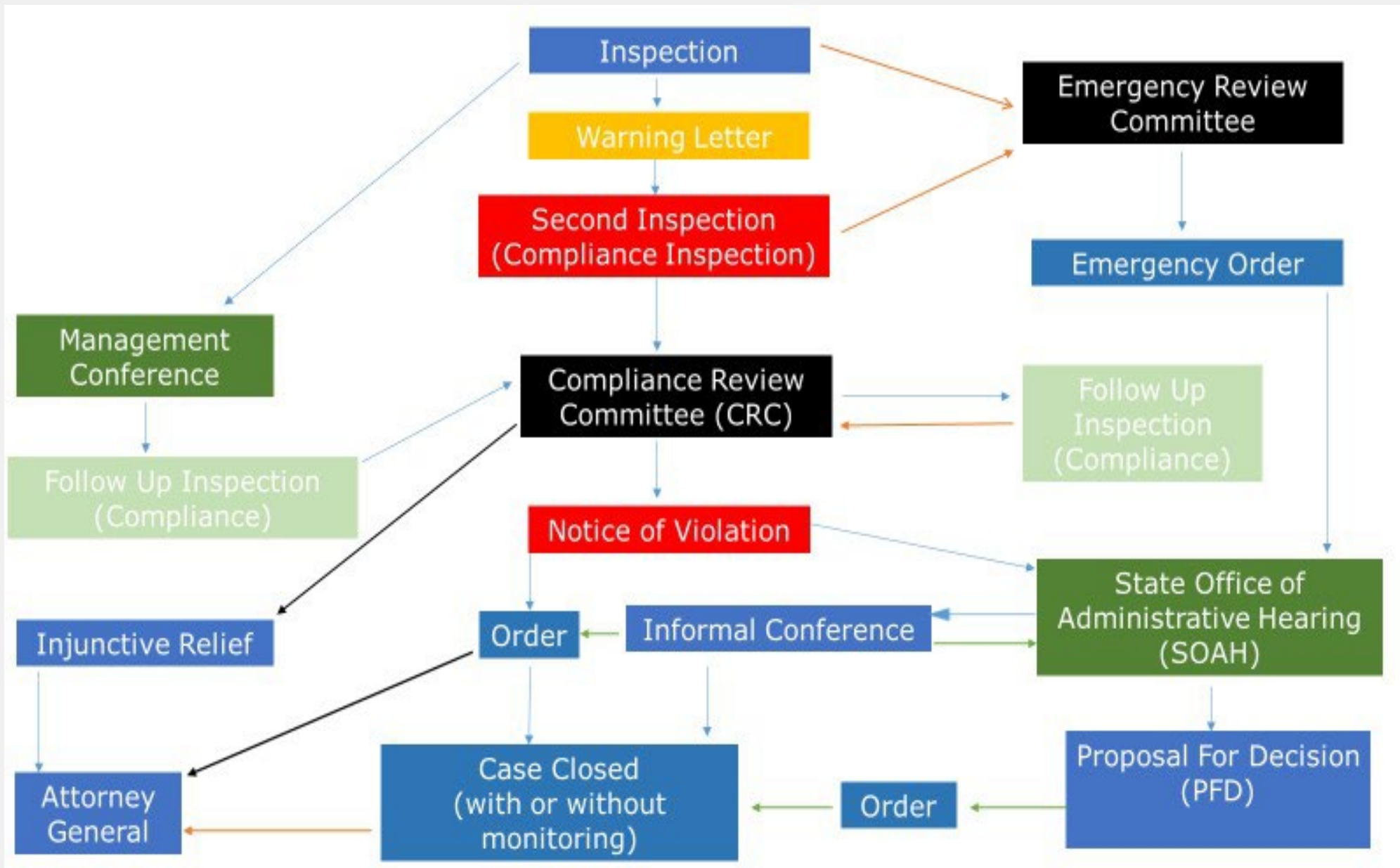
PDPD License Type

7700 - Prescription Drug Price Disclosure Program



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PDPD Compliance Flowchart



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Cases referred to Compliance

- Fourteen (14) cases were referred in total:
 - Fourteen (14) cases were license only cases that required no Compliance Review Committee (CRC)

License Only	14
Total	14



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Outcomes

After review:

- Eleven (11) Notice of Violation (NOV) letters were cleared to be issued
- Three (3) cases were returned to program



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Informal Conference (IC)

No case was held at an IC



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State Office of Administrative Hearings (SOAH)

Compliance referred zero (0) cases to SOAH, at the request of the Respondent pursuant to HSC Sec. 441.0103 and Chapter 2001, Government Code.

SOAH REFERRAL	0
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- ❖ All Respondents were offered the opportunity to have their case(s) presented before an Administrative Law Judge.

Orders & Agreements Processed

- Fourteen (14) 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.



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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 : 0

Cases closed without monitoring: 28

Cases withdrawn: 3

Penalty Amount Proposed/ Assessed

\$5,800.00



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Penalty Amount Remitted/Collected

\$2,900.00



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Thank You



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