COMPLIANCE SECTION CONSUMER SAFETY BRANCH

PRESCRIPTION DRUG PRICE DISCLOSURE



FY-24 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 Administrationapproved 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

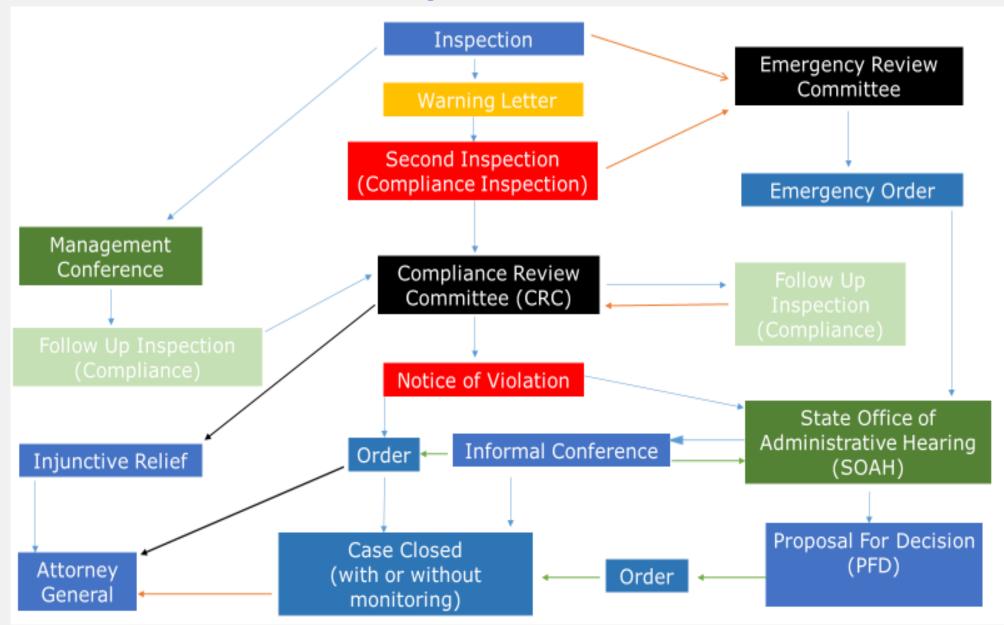
https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview

PDPD License Type

7700 - Prescription Drug Price Disclosure Program



PDPD Compliance Flowchart





FY24 Cases referred to Compliance

Thirty-three (33) cases were referred in total



FY24 Notice of Violations Issued

• Thirty three (33) Notice of Violation (NOV) letters were issued



Informal Conference (IC)

No case was held at an IC



State Office of Administrative Hearings (SOAH)

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

SOAH REFERRAL

0

Orders

Twenty-three (23) Orders were processed

Acceptance - 17

Agreed – 2

Default-4



Attorney General (AG) Referrals

• Three (3) cases were 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

- Two (2) cases were closed with monitoring
 - Terms and conditions to be met are still pending
- Twenty-eight (28) cases were closed without monitoring
 - All terms and conditions are met

Grand Total Penalty Amount Assessed

\$5,700.00



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

<u>Compliance Section - Consumer_Safety_Branch_Procedure_Manual.pdf - All Documents (sharepoint.com)</u>

Thank You