

FDA Tobacco Inspection Program

By Season Eckstrom, FDA Program Coordinator

Background on the FDA Program

- ▶ The Family Smoking Prevention and Tobacco Control Act (commonly referred to as Tobacco Control Act) was signed into law June 22, 2009, giving FDA the authority to regulate the manufacture, distribution and marketing of tobacco products.
- ▶ FDA's Center for Tobacco Products (CTP) issues contracts to states to assist with compliance check inspections of retail establishments to determine a retailer's compliance with federal laws and regulations
- ▶ LCB's first state contract with the FDA began in September 2010
 - ▶ WA was one of 15 states to pilot this program
 - ▶ The program utilized FDA commissioned LEOs (used on a part time basis)
 - ▶ 1 year contract and checked approximately 20% of tobacco retailers
 - ▶ Program continued to evolve and now employs a full-time FDA Program Coordinator and 6 full-time inspectors across the state

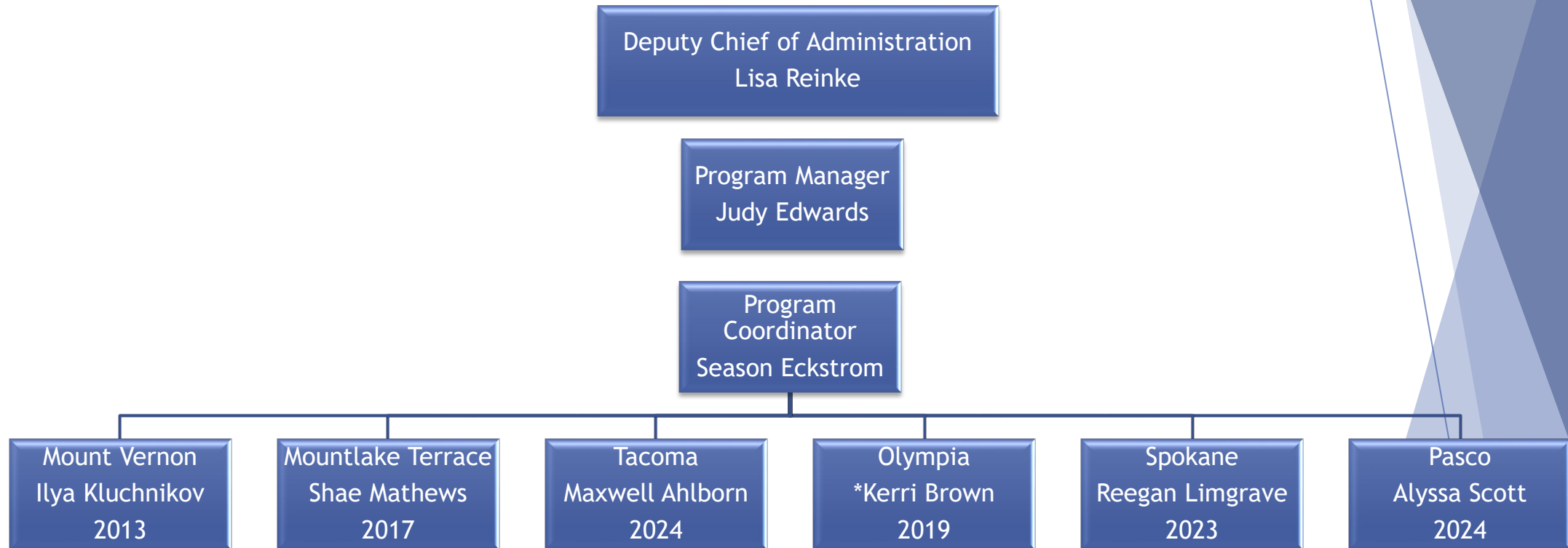
Contract Overview

- ▶ LCB is currently in a 4-year contract with the FDA
 - ▶ Base Year and 3 Option Years
 - ▶ Each option year requires a signed modification to execute to the updated terms of the new year
 - ▶ Current 4-year Contract ends May 29, 2025
 - ▶ Anticipate the next RFP will post beginning of 2025
 - ▶ LCB will submit an approximately 45-page response that includes a Technical Proposal, Business Proposal, and Past Performance.
 - ▶ Not competing against any other agencies in WA State
- ▶ Our Program is fully funded by the FDA
 - ▶ Invoices are submitted monthly
 - ▶ Costs must be outlined in the contract
- ▶ The FDA's goal is to establish a contract with states agencies in every U.S. state and territory.
 - ▶ Contracts are awarded to third-party entities to conduct compliance checks in states where they have been unable to secure contracts with state agencies.

FDA Site Visits

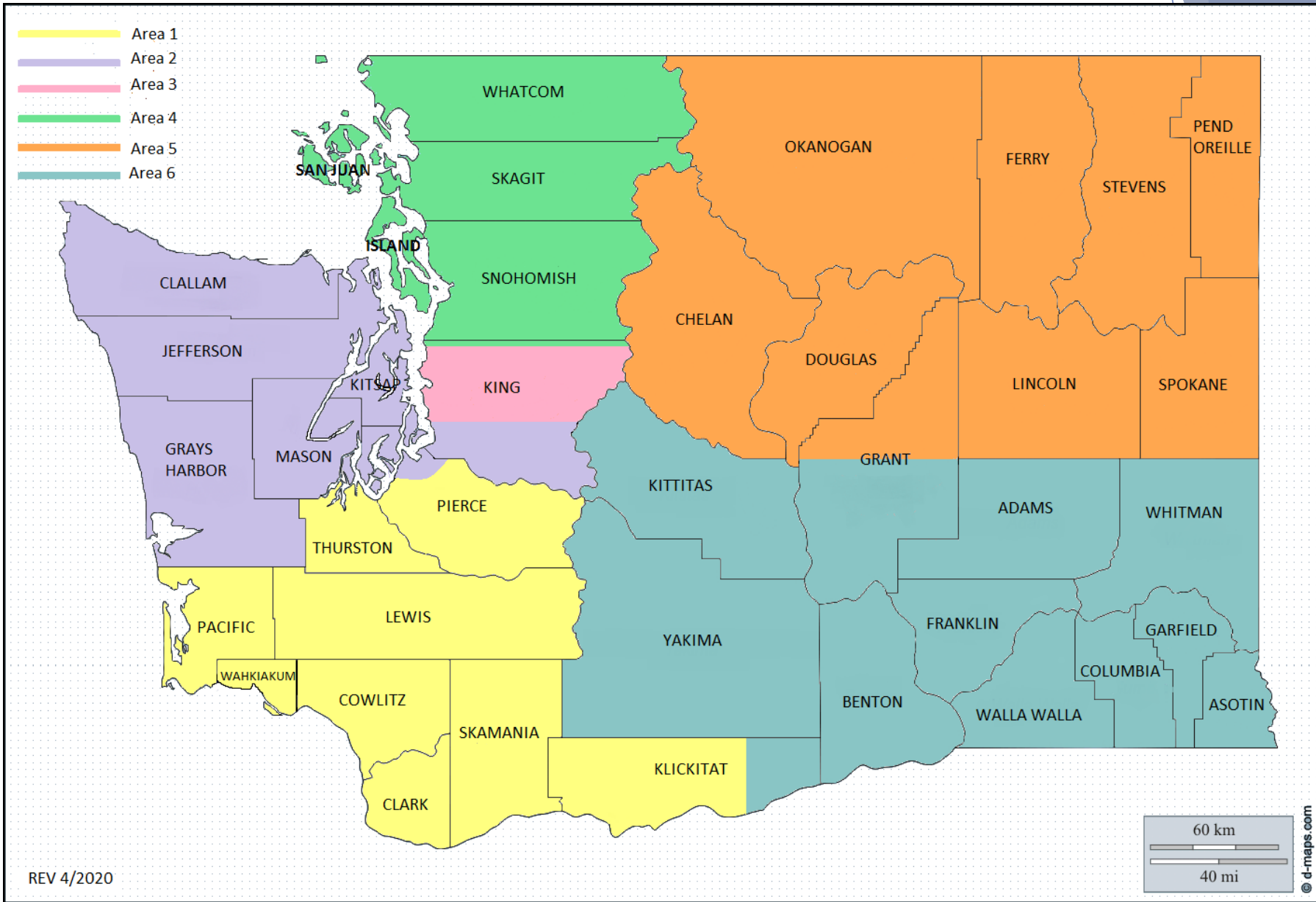
- ▶ FDA conducts site visits every 2 years
 - ▶ Contract Review
 - ▶ Program Review
 - ▶ Looking over policies and procedures related to how the program is managed
 - ▶ Personnel file audits
 - ▶ Inspectors and investigative aides (IAs)
 - ▶ Evidence audit
- ▶ Most recent site visit was May 2024
 - ▶ Site visit completed with no findings or issues

FDA Org Chart



Overview of the FDA Program

- ▶ Housed in the Enforcement and Education Division
- ▶ FDA Program Coordinator (PC) Season Eckstrom
 - ▶ Started with the FDA Program in January 2017
- ▶ Back-Up Program Coordinator (BPC)
 - ▶ A full-time inspector, trained on PC duties for coverage when needed
- ▶ 6 full-time inspectors across the state
- ▶ All inspection data is tracked in FDA's Tobacco Inspection Management System (TIMS)
 - ▶ PC and FDA Inspectors are the only ones who have access to this system
 - ▶ PC and BPC have FDA issued laptop to manage all FDA related work and communication with FDA directly



What Do FDA Inspectors Do

- ▶ The FDA Tobacco Inspectors conduct inspections at all Washington state tobacco product retail locations to determine compliance with federal laws and regulations, including the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Tobacco Control Act
- ▶ 6-week field training program for inspectors, which also including extensive online training and testing created by the FDA
- ▶ Our goal is to conduct one inspection at every tobacco retailer in the state each year
 - ▶ If the retailer remains in compliance, we will not check more than once per year
 - ▶ If the retailer is out of compliance the FDA may assign follow-up inspections, resulting in multiple checks per year
- ▶ Approximately 85% of the inspector's work is in completed in the field
- ▶ All inspections and reports are completed on an FDA iPhone connected to the federal system, TIMS
- ▶ Two Types of Inspections - Undercover Buys and Advertising and Labeling Inspections

Undercover Buys (UB) Inspections

- ▶ Accounts for approximately 80% of our inspections
- ▶ Conducted to determine compliance with federal laws pertaining to youth access, sale of tobacco products to underage persons, and age verification requirements
- ▶ Investigative aide attempts to purchase a pre-determined tobacco product
- ▶ No sale - the IA and inspector exit the establishment and the inspector documents accordingly
- ▶ Sale - the inspector and IA exit the establishment and go to a safe location to complete their inspection narrative reports and process the evidence
- ▶ No contact is made with the licensee, even if a sale occurs
- ▶ Notification of the sale and follow up is sent out by the FDA
- ▶ Our current compliance rate is approximately 85%

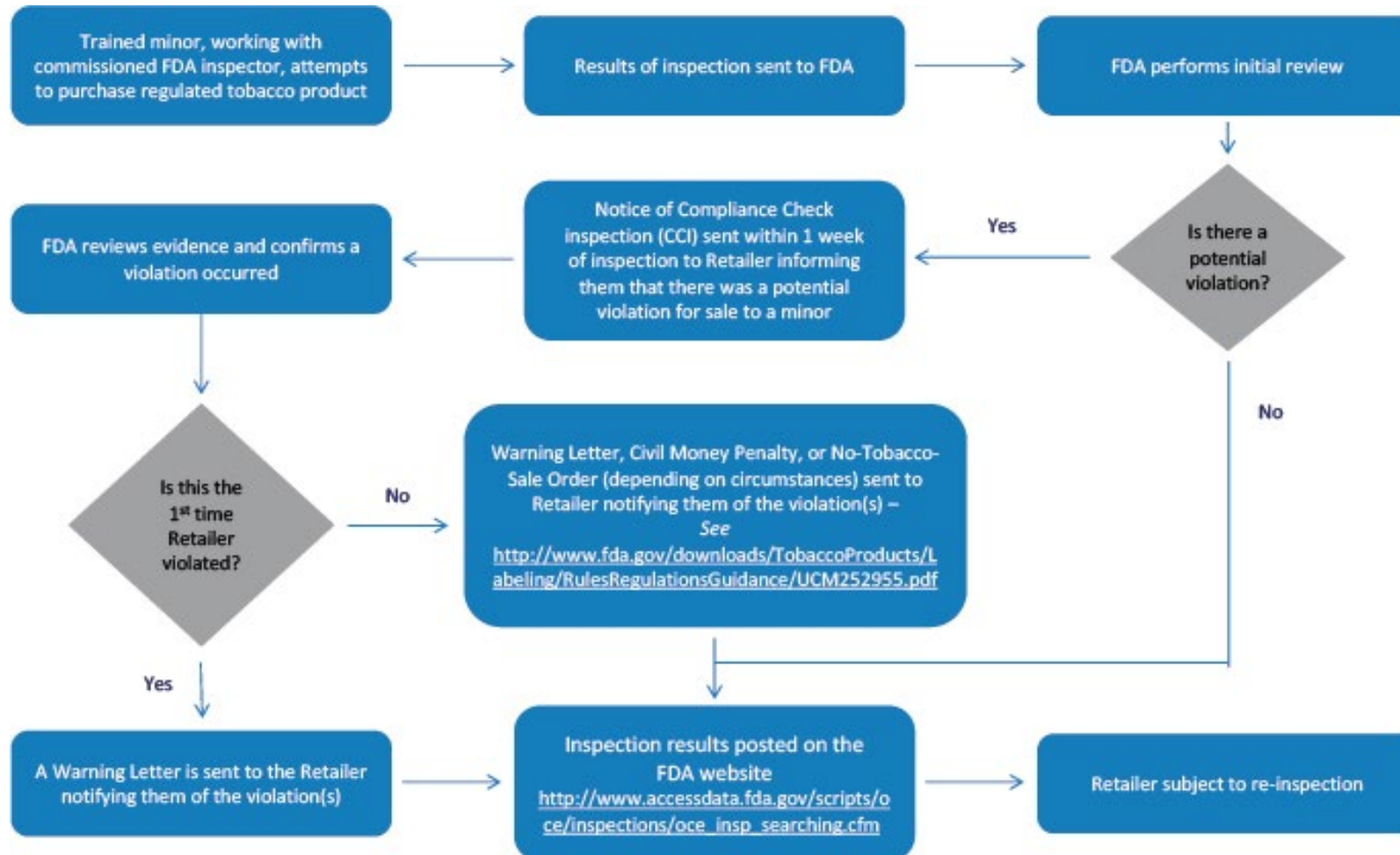
Advertising and Labeling (A&L) Inspections

- ▶ Account for approximately 20% of our total inspections
- ▶ A&L inspections are typically only conducted at retailers who have been out of compliance (usually this means they have previously sold to an underage person)
- ▶ The FDA Inspector introduces themselves and issues a Notice of Inspection (Form 482)
- ▶ These inspections are used to determine retailer compliance with federal regulations and laws, beyond youth access
 - ▶ Advertising and warning label requirements
 - ▶ Sale of unauthorized products or unauthorized product placement
 - ▶ Verify business ownership and location information

No Tobacco Sales Order (NTSO) Inspections

- ▶ The FDA may pursue a no-tobacco-sale order (NTSO) against retailers that have a total of five or more repeated violations of certain restrictions within 36 months
 - ▶ Retailers are prohibited from selling regulated tobacco products at the specified location during the period of the NTSO
- ▶ The FDA may assign NTSO inspections during this period to determine retailer compliance
- ▶ Inspectors conduct the NTSO inspections
- ▶ Only 8 NTSOs issued in Washington

What Happens if a Potential Violation occurs?



Monetary Penalties

Number of Regulation Violations	CMP Amount
1	\$0 (CTP will send a Warning Letter)
2 within a 12-month period	\$356
3 within a 24-month period	\$709
4 within a 24-month period	\$2,846
5 within a 36-month period	\$7,115
6 within a 48-month period	\$14,232

*Additionally, the maximum penalty amount for violating a requirement of the FD&C Act relating to tobacco products is \$21,348 for a single violation. FDA intends to seek the maximum allowed by law in CMP cases relating to unauthorized tobacco products.

Tobacco Compliance Check Outcomes

(includes decisions through 08/31/2024)

This database includes inspections of brick-and-mortar retailers and online investigations.

Brick-and-Mortar Inspections

Online Investigations

Search Decisions

Retailer Name

Outcome

Underage Purchaser (UP) Involved

City

Decision Date

From

To

Sale to UP

State

Zip

Product Type Purchased by UP

Search

Clear Form

FDA Compliance Check Stats

	1 st Quarter	2 nd Quarter	3 rd Quarter
Total Completed Checks	1018	1147	1062
A&Ls	258	213	233
UBS	760	934*	829
PVOs for Sale to minor	129	127	123
Compliance Rate	83%	86%	85%
Incomplete Inspections	98	97	117

* 1 NTSO follow-up completed in June 2024

Questions?