

Vaccine procurement

Vaccine storage and handling

Temperature monitoring

Vaccine management practices to minimize loss and waste

Site Visits



BOOSTER CLUB

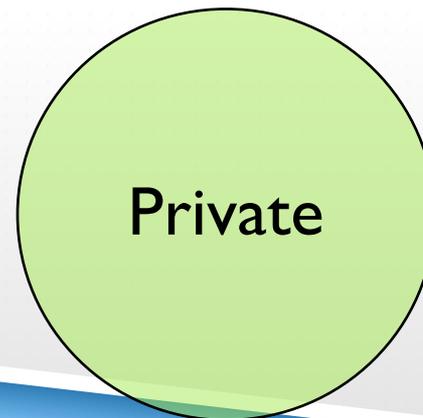
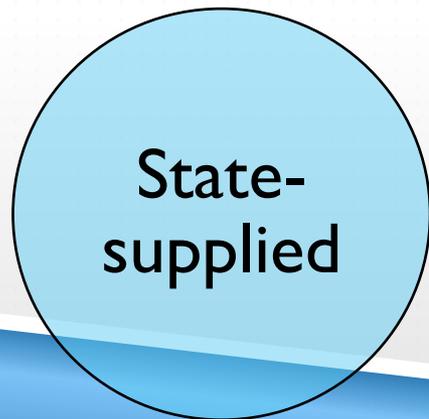
VACCINE PROCUREMENT

Matthew Bobo



VACCINE PROCUREMENT

- ▶ Vaccine procurement is the process of acquiring vaccines
- ▶ The objective of vaccine procurement is to receive products of assured quality at affordable prices in a timely manner
- ▶ Vaccine costs continue to increase
 - ▶ To vaccinate a child thru 18 years cost \$45 in 1985 to over \$1,700 in 2012
- ▶ State-supplied vaccine vs. Privately purchased vaccine



State-supplied Vaccines: Children

Vaccine	Brand Name	NDC
DTaP	Infanrix	58160-0810-11
DTaP/Hep B/IPV	Pediarix	58160-0811-52
DTaP/IPV	Kinrix	58160-0812-11
Hep A	Havrix	58160-0825-11
Hep B	Recombivax	00006-4981-00
Hib - PRP-OMP	PedvaxHIB	00006-4897-00
9vHPV	Gardasil	00006-4119-03
Influenza	<i>Varies[†]</i>	
IPV	IPOL	49281-0860-10
MCV4	Menactra	49281-0589-05
MENB	TBD	
MMR	M-M-R II	00006-4681-00
PCV13	Prevnar 13	00005-1971-02
Rotavirus	RotaTeq	00006-4047-41
Tdap	Boostrix	58160-0842-11
Varicella	Varivax	00006-4827-00

[†]Influenza brand names vary each influenza season

State-supplied Vaccines: Adults

Vaccine	Brand Name	NDC
9vHPV (females, 19-26 yrs; males, 19-21 yrs; high risk males*, 22-26 yrs)	Gardasil	00006-4119-03
Influenza	<i>Varies[†]</i>	
MCV4 (19-20 yrs)	Menactra	49281-0589-05
PPSV23	Pneumovax 23	00006-4943-00
Td	Tenivac	49281-0215-10
Tdap	Boostrix	58160-0842-11
Zoster (60-64 yrs)	Zostavax	00006-4963-41

*High risk males include immunocompromised men and men who have sex with men (MSM)

[†]Influenza brand names vary each influenza season

STATE-SUPPLIED VACCINE: FINANCING

Vaccine for Children (VFC) Program

- ▶ Funding Source = **FEDERAL**
- ▶ Federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay
- ▶ A child is eligible for the VFC Program if he or she is younger than 19 years of age and is one of the following:
 - ▶ Medicaid-eligible
 - ▶ Uninsured
 - ▶ Underinsured (Federally Qualified Health Center [FQHC])
 - ▶ American Indian or Alaska Native
- ▶ Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines

STATE-SUPPLIED VACCINE: FINANCING

Section 317 Funds

- ▶ Funding Source = **FEDERAL**
- ▶ Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults.
- ▶ Section 317-funded vaccines can be used to vaccinate:
 - ▶ Newborns receiving the birth dose of hepatitis B prior to hospital discharge
 - ▶ Fully insured infants of hepatitis B infected women and the household or sexual contacts of hepatitis B infected individuals
 - ▶ Uninsured or underinsured adults
 - ▶ Fully insured individuals seeking vaccines during public health response activities (i.e., outbreak response, post-exposure prophylaxis, disaster relief efforts, and mass vaccination campaigns)
 - ▶ Individuals in correctional facilities and jails
- ▶ Since 2009, Alaska has seen a decrease in annual Section 317 funds from \$4 million to less than \$200,000 in 2015.

STATE-SUPPLIED VACCINE: FINANCING

Governor's Increase

- ▶ Funding Source = **STATE**
- ▶ Passed each legislative session
- ▶ Approximately \$700,000/year
- ▶ Funding source not guaranteed

STATE-SUPPLIED VACCINE: FINANCING

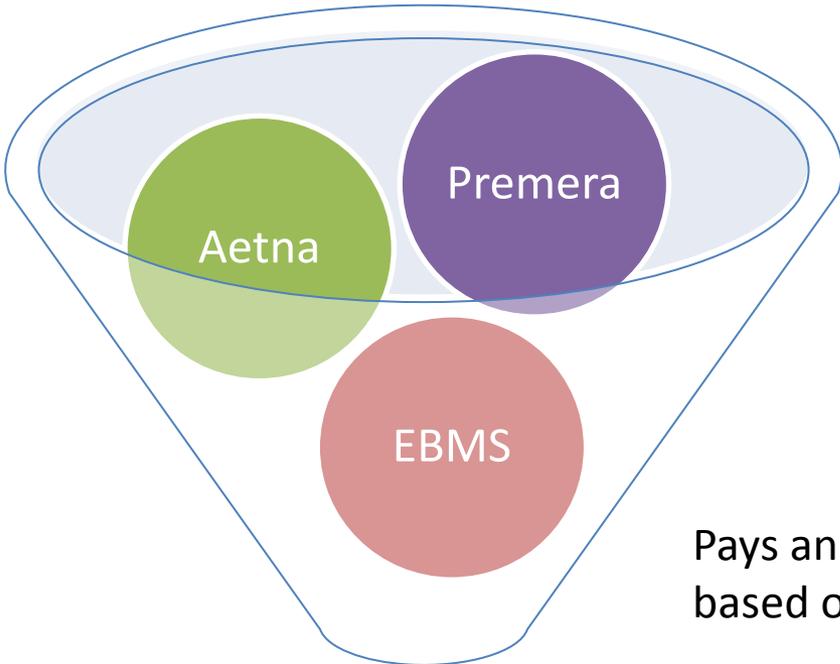
Alaska Vaccine Assessment Program (AVAP)

- ▶ Funding Source = **OTHER**
- ▶ Funding mechanism by which:
 - ▶ Healthcare insurers and other payers pay an assessment based on their proportionate share of the overall vaccine costs
 - ▶ Account funds are remitted to the Alaska Immunization Program to purchase vaccine and distribute to providers
- ▶ Three year phase-in during which payers can opt-out
- ▶ Providers can opt-in to cover uninsured adults

7 * **Section 1.** AS 18.09 is amended by adding new sections to read:

8 **Article 1A. Statewide Immunization Program.**

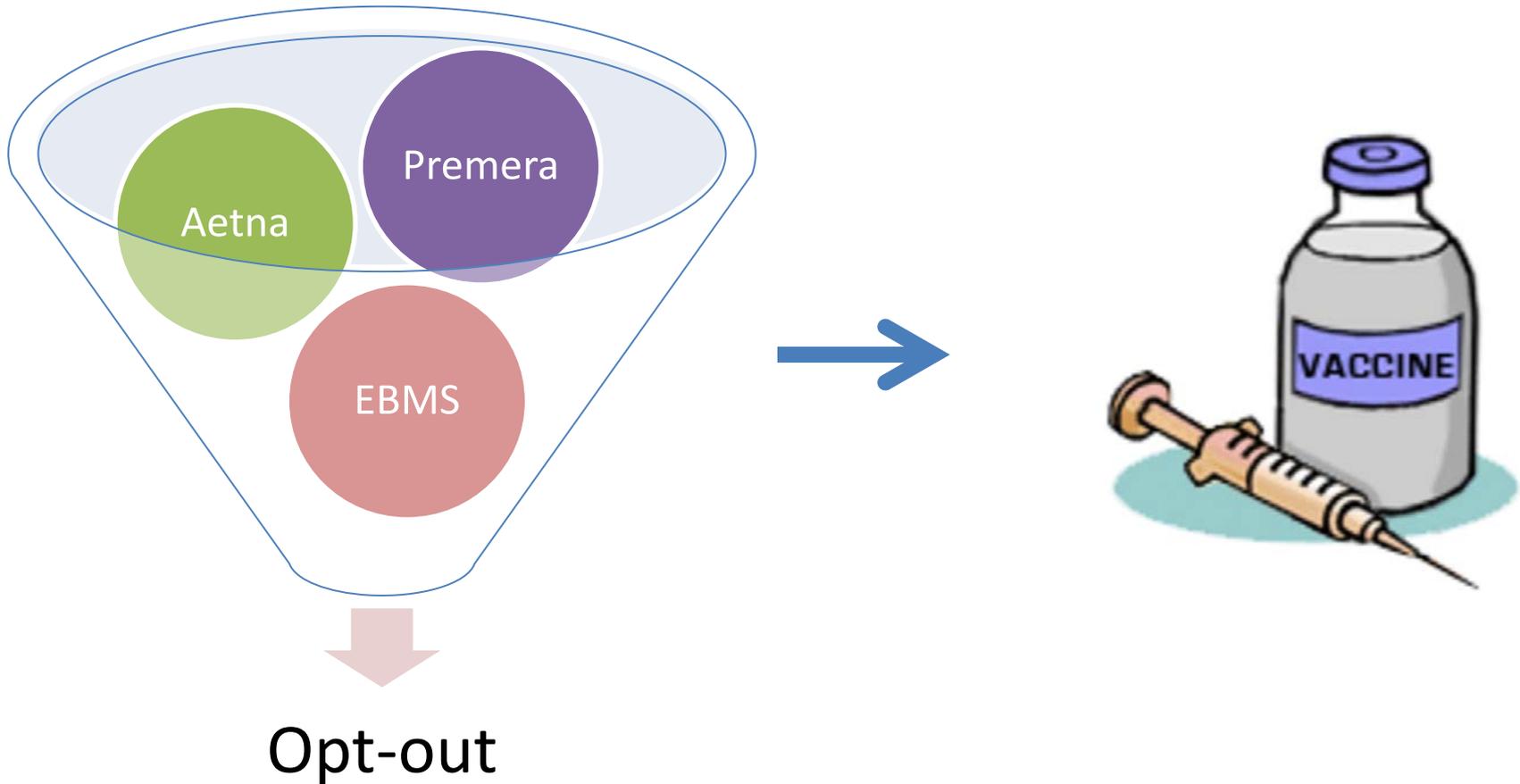
9 **Sec. 18.09.200. Statewide immunization program established;**
10 **commissioner's duties.** (a) In addition to health promotion and vaccine registration
11 activities of the department, a statewide immunization program is established in the
12 department for the purpose of monitoring, purchasing, and distributing included
13 vaccines to providers approved by the department who agree to provide the included
14 vaccines to state residents under terms consistent with the program and state and

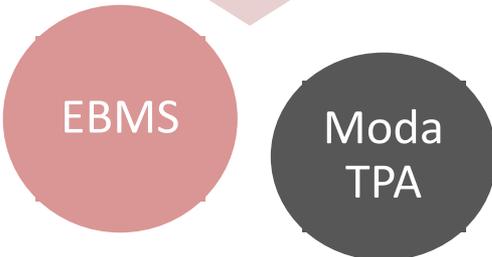
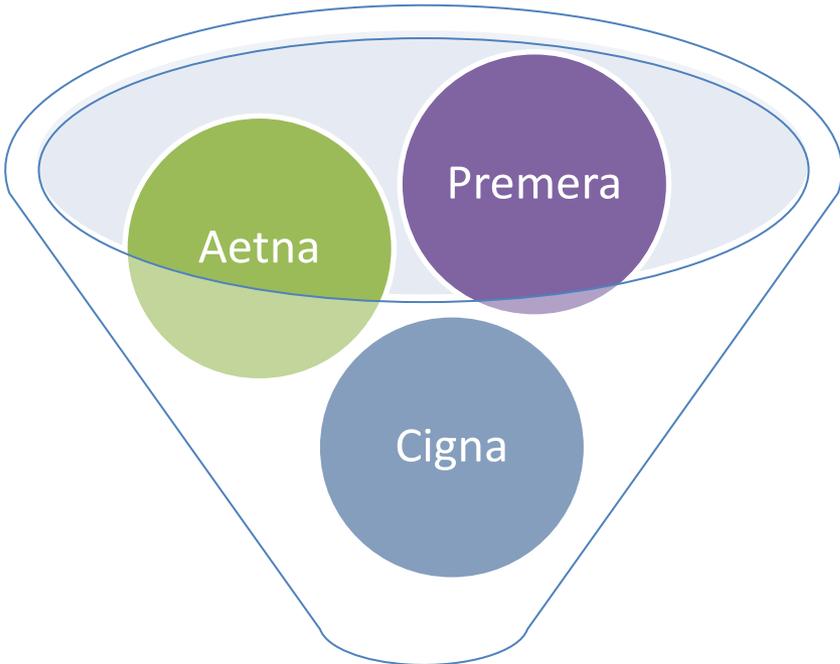


Pays an assessment
based on covered lives

2015 Assessment Rate
\$6.85 / child / month
\$0.98 / adult / month

4 (e) An assessable entity may opt out of the program during the three-year
5 phase-in period under procedures approved by the commissioner.





2015 AVAP PAYER OPT-OUT

- ▶ Over 100 participating payers, including: Premera, Aetna, United Healthcare, Cigna, etc.
- ▶ Opt-out payers in Year 1
 - ▶ EBMS (Employee Benefit Management Services, Inc.)
 - ▶ Municipality of Anchorage Employees – Moda TPA Plan
 - ▶ Blue Benefit Massachusetts
 - ▶ Seafarers Health
 - ▶ State Farm Mutual Auto Insurance
- ▶ Non-participating payers
 - ▶ Medicaid
 - ▶ Medicare
 - ▶ TRICARE

2015 CHILD STATE-SUPPLIED VACCINES

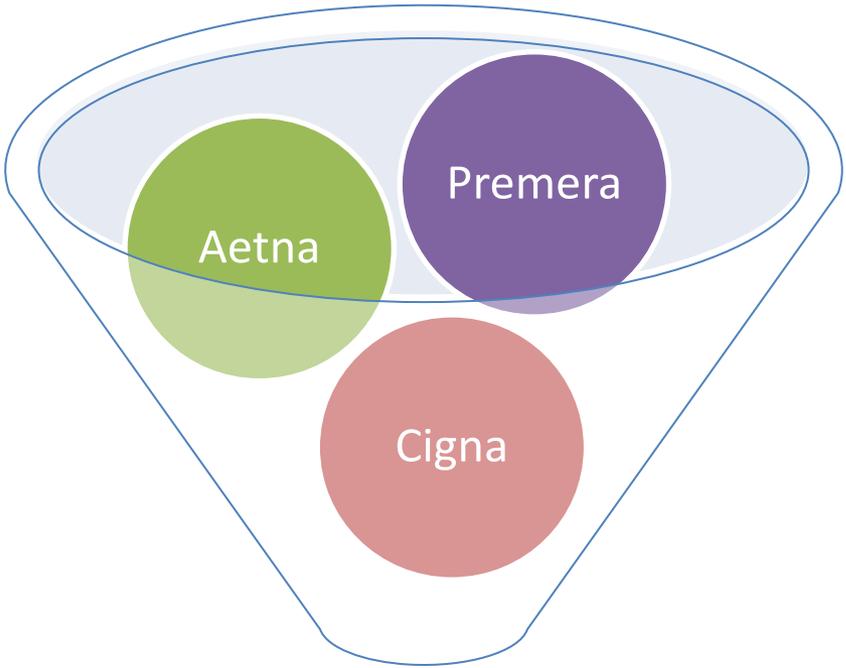
- ▶ Providers can receive **all** ACIP recommended childhood vaccines
 - ▶ VFC-eligible children (Funding Source = VFC)
 - ▶ Children with participating payers (Funding Source = AVAP)
 - ▶ Children with non-participating or opt-out payers (Funding Source = Residual SOA Funds)

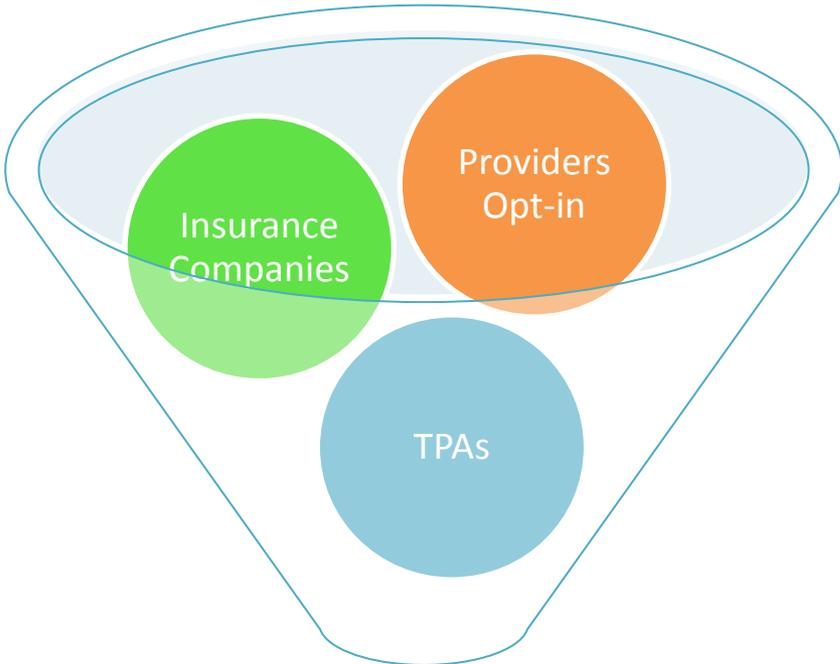
2015 ADULT STATE-SUPPLIED VACCINES

- ▶ Providers who opt-in for uninsured adults can receive state-supplied vaccine for:
 - ▶ Participating payers
 - ▶ Uninsured
 - ▶ Opt-out payers
 - ▶ Non-participating payers
- ▶ All other providers can receive state-supplied vaccine **only** for:
 - ▶ Participating payers
 - ▶ Medicaid

Provider
Opt-in

Provider estimates their total
number of uninsured adults



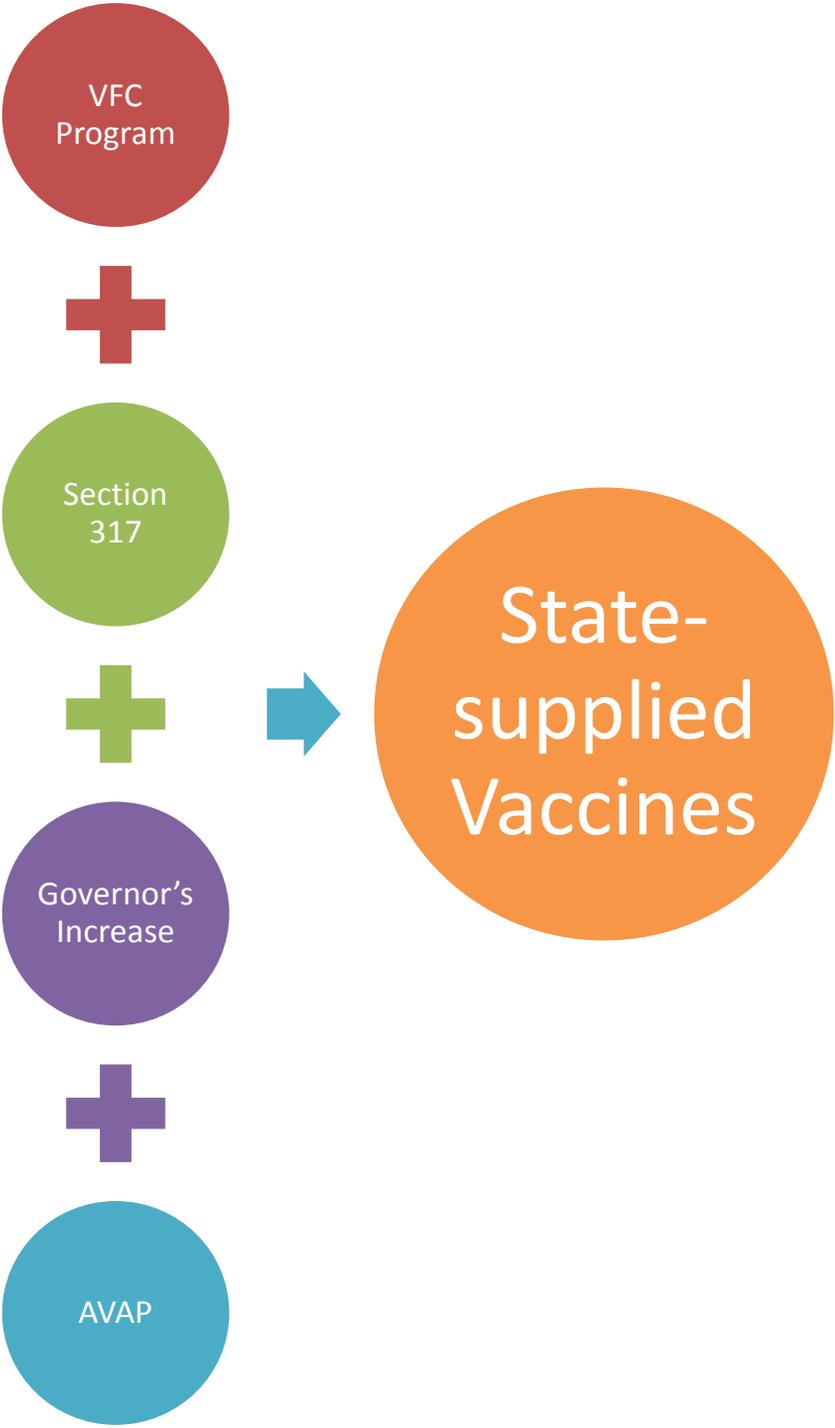


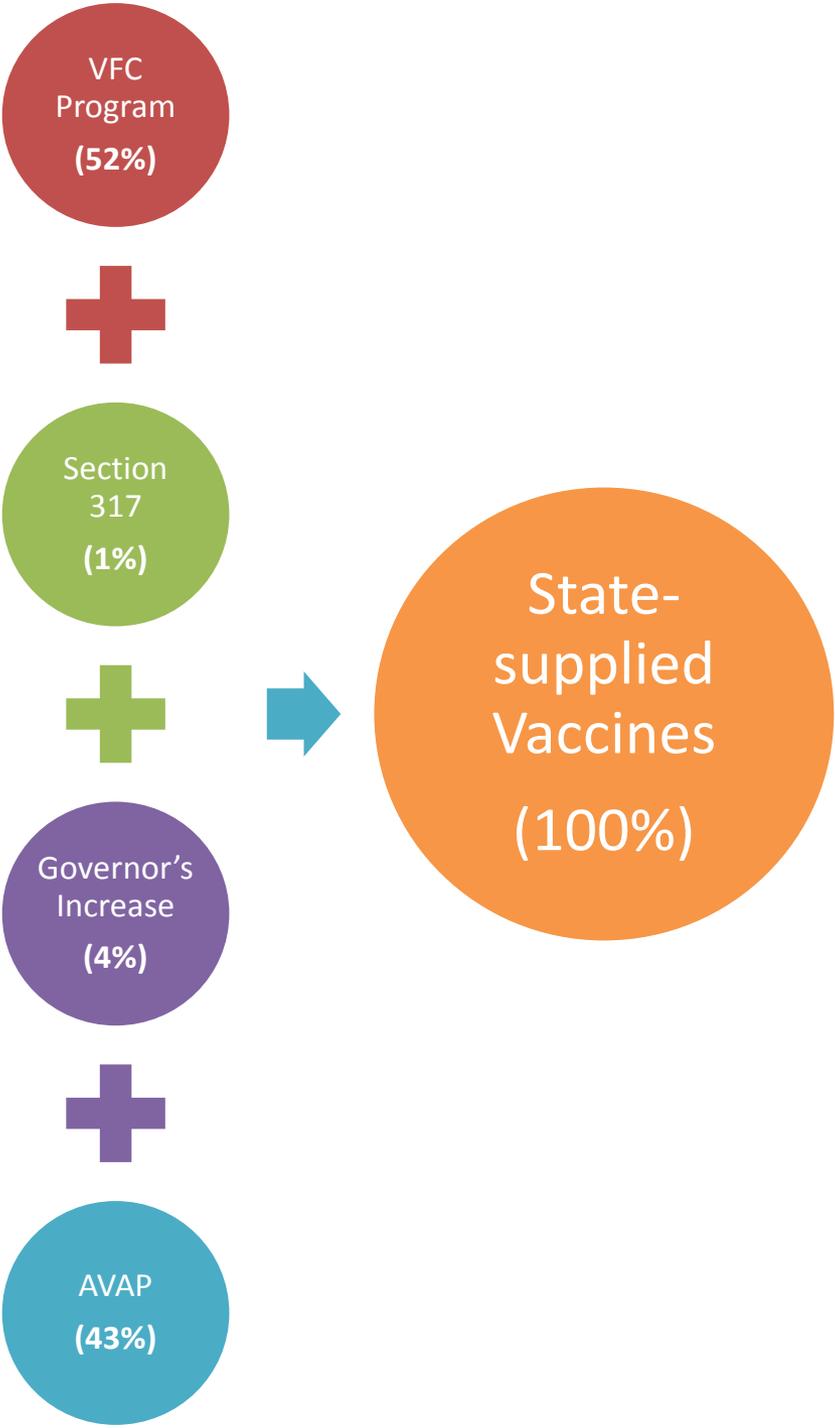
2015 ADULT STATE-SUPPLIED VACCINES

- ▶ Providers who opt-in for uninsured adults can receive state-supplied vaccine for:
 - ▶ Participating payers
 - ▶ Uninsured
 - ▶ Opt-out payers
 - ▶ Non-participating payers
- ▶ All other providers can receive state-supplied vaccine **only** for:
 - ▶ Participating payers
 - ▶ Medicaid

LOOKING TOWARDS 2016

- ▶ 2016 Assessment Methodology = Covered Lives
- ▶ Adult state-supplied vaccines will remain the same
- ▶ 2016 Opt-out Deadline was September 29, 2015
- ▶ 2016 Opt-outs include (as of 09/30/15):
 - ▶ Employees Painters' Trust Health and Welfare Plan
 - ▶ Covered Lives = 530
 - ▶ Seattle Area Plumbing and Pipe Fitting Industry Health Trust
 - ▶ Covered Lives = 2
 - ▶ Prudential Insurance Company of America
 - ▶ Covered Lives = 4
 - ▶ EBMS (Employee Benefit Management Services)
 - ▶ Covered Lives = 20,840

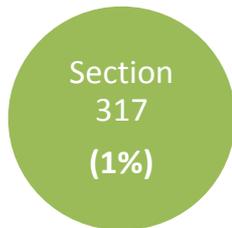




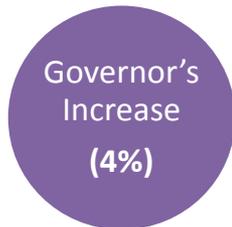
\$9.2 million



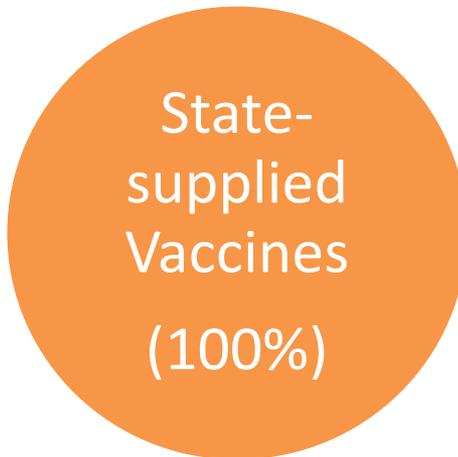
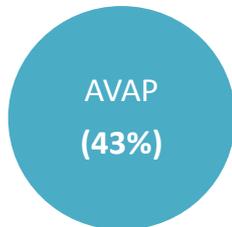
\$186,151



\$700,000



\$7.6 million



\$17.7 million

VACCINE STORAGE AND HANDLING

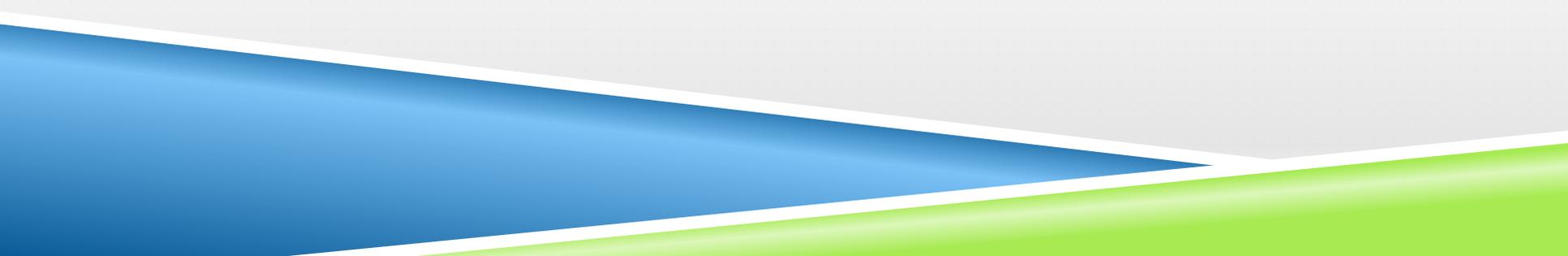
Alicia Spillman



DIVISION OF PUBLIC HEALTH
SECTION OF EPIDEMIOLOGY



THE IMPORTANCE OF PROPER VACCINE STORAGE AND HANDLING

- ▶ Exposure to warm or cold temperatures can affect the potency, shorten the expiration date or destroy vaccines
 - ▶ Recalling patients to repeat vaccine doses means extra doses for patients, inconvenience, increased cost and staff time for providers
 - ▶ Damage to public confidence in vaccines
 - ▶ Vaccines are expensive
- 

STORAGE UNITS

- ▶ Acceptable 
 - ▶ Pharmaceutical stand alone or combination unit
 - ▶ Stand alone refrigerator
 - ▶ Stand alone freezer
 - ▶ Refrigerator compartment of a household or commercial combination unit
 - ▶ Counter top freezer, under the counter freezer or compact freezer
 - ▶ Prohibited 
 - ▶ Dorm style fridge
 - ▶ Freezer compartment of a household or commercial combination unit
-  *New requirement starting in 2016*

STORAGE UNITS



Pharmaceutical Unit



Stand-alone freezer



Stand-alone counter top freezer



Chest freezer



Freezer compartment of commercial or household combination unit prohibited



Dormitory-style unit prohibited



PURCHASING A NEW STORAGE UNIT

- ▶ Purchasing a new storage unit
 - ▶ Refrigerator must maintain temperatures between 35-46 F at all times
 - ▶ Freezer must maintain temperatures between -58 and +5 F at all times
 - ▶ A fluctuation of no more than 4 degrees is preferred
 - ▶ Frost-free units with an automatic defrost cycle is preferred
 - ▶ Large enough unit to store the year's largest inventory without crowding
 - ▶ Self-closing doors and alarms that detect door ajar are helpful in preventing temperature excursions

SETTING UP A NEW STORAGE UNIT

- ▶ Setting up a new storage unit
 - ▶ Place unit in a well-ventilated room with space around the sides and top of unit
 - ▶ Remove any drawers
 - ▶ Store water bottles in refrigerator and frozen water bottles in freezer to stabilize temperatures
 - ▶ Post a “Do not unplug” sticker or sign on the unit, the outlet in use and the circuit breaker
 - ▶ Post a printed twice a day temperature log on the unit
 - ▶ Submit a week of LogTag temperature readings to the Vaccine Depot for approval prior to moving vaccine into new unit
 - ▶ Freezer compartment of combination unit is to remain on to maintain proper temperatures in the refrigerator compartment



VACCINE STORAGE AND HANDLING

- ▶ Place the vaccines and the temperature monitoring device in the center of the storage unit, leaving adequate space for air circulation
 - ▶ Do not place in the doors, near or against the walls or on the floor of the unit.
- ▶ Do not place the vaccine or temperature monitoring device directly under the fan or the vent that blows air from the freezer
- ▶ Store all vaccines in the original box
- ▶ State-supplied vaccines must be segregated and/or marked so that they are easily distinguished from privately purchased vaccines
- ▶ Do not store food or drink in vaccine storage unit
- ▶ Place water bottles in the refrigerator and gel packs in the freezer
- ▶ Rotate stock according to expiration date

STORAGE UNIT EXAMPLES

► Pic #1 - Observations?



STORAGE UNIT EXAMPLES

► Pic #2-
Observations?



STORAGE UNIT EXAMPLES

- ▶ Pic #3- Observations?



STORAGE UNIT EXAMPLES

- ▶ Pic #4- Observations?



VACCINE TEMPERATURE MONITORING

- ▶ Document temperatures twice a day on the state-specific Temperature Log on all storage units containing state-supplied vaccine
 - ▶ Record the time of day, initials, alarm status and current temperature from the LogTag
- ▶ The Temperature Logs must be made readily available to the Alaska Immunization Program upon request



TEMPERATURE LOG

Protect Your Vaccines. Check Temperatures Twice a Day!

Facility Name _____ Mo/Yr _____ PIN _____ DAYS 1-15

Instructions: Insert the day, time, and your initials in the designated boxes. Mark an "X" in the box that corresponds to your temperature reading. Write an "N" or "Y" for both refrigerator and freezer to verify that you reviewed the alarm status on the temperature monitoring device(s). An "N" means that there is no alarm and a "Y" means that the word "alarm" is displayed on the temperature monitoring device screen. If you mark "Y" or if you record a temperature in the shaded zone, follow the instructions below.

THE SHADED ZONES REPRESENT UNACCEPTABLE TEMPERATURES! *If a temperature recorded here is unacceptable or if there is an alarm status on the temperature monitoring device:*

1. Store the vaccine under proper conditions as quickly as possible. (Segregate the vaccine and identify it as "DO NOT USE" while vaccine viability is being determined).
2. Immediately download and review the graph.
3. Contact the Epidemiology Vaccine Depot at 907-341-2202 to determine whether the potency of the vaccine has been affected.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Day of Week																														
Time of Day	am	pm																												
Staff Initials																														
Alarm N or Y																														
≥48°																														
47°																														
46°																														
45°																														
DO NOT USE vaccines that have been stored at these temperatures! See instructions at top of page.																														

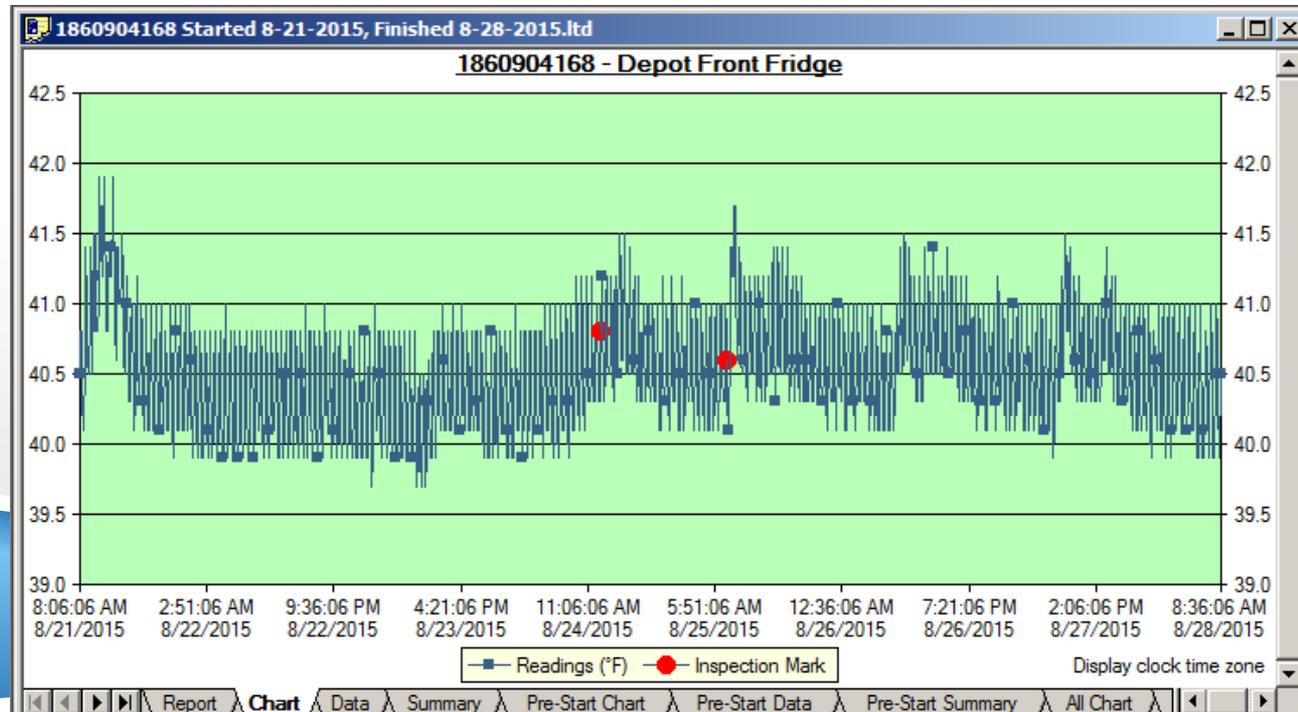
LOGTAG

- ▶ Temperatures in all permanent storage units storing state-supplied vaccine must be monitored using the calibrated LogTag TRED 30-7 and interface cradle provided by the Alaska Immunization Program
- ▶ Required to have a back-up calibrated continuous monitoring device on hand in case of emergency or vaccine transport
 - ▶ Previous state-supplied LogTags may be calibrated for use as a back-up device



LOGTAG

- ▶ Document the temperature twice a day on the Temperature Log
- ▶ Check alarm status
- ▶ Press the Review button to view the daily min/max
- ▶ Download the graph weekly and email to vaccinedepot@alaska.gov
- ▶ Check battery status on display screen and on downloaded graph
- ▶ Change battery



LOGTAG DISPLAY SCREEN

- ▶ Alarm notification on the LogTag display screen



- ▶ Battery status on the LogTag display screen

LOGTAG DOWNLOAD

- ▶ Battery status on the graph and configuration

LogTag Recorder has been downloaded 3/5/2014 7:33:41 AM (UTC-09:00, stan...

Alarm Status Recorder Info

Low <input checked="" type="checkbox"/> OK	Serial #: 1060001671	Model: TRED30-7R	Battery: OK	Trip #: 26
High <input checked="" type="checkbox"/> OK	User ID: 100773 Refrigerator			

Recorder Configuration

Start type: Push button start	Temperature alarms
Start delay: 5 Minutes	Lower: 35.5 °F
Interval: 5 Minutes	Upper: 46.9 °F
Alarm indicator: Enabled lower & upper	

Recorded Data

First reading: 3/3/2014 4:52:52 PM	Temperature statistics
Last reading: 3/5/2014 7:32:52 AM	Lowest: 39.4 °F
Elapsed Time: 1 Day, 14 Hours, 40 Minutes	@ 3/4/2014 9:12:52 A
Total readings: 466	Highest: 42.3 °F
First evaluated: 3/3/2014 4:52:52 PM	@ 3/4/2014 3:42:52 P
Last evaluated: 3/5/2014 7:32:52 AM	Average reading: 40.7 °F
	Standard Deviation (S): 0.7 °F
	MKT(ΔH: 83.144): 40.68 °F

Low Alarm High Alarm

Report Chart Data Summary Pre-StartChart Pre-StartData Pre-StartSum

LogTag Configure

User ID: Ted's LT12-159

Push button start **LogTag battery: OK**

Enable pre-start logging

Record readings continuously, overwrite oldest when memory full

Record readings go that:

Readings recorded will span at least 27 days

Number of readings to record 7,777 maximum is 7777

Record a reading every 5 Minutes

Begin recording after a delay of 5 Minutes

Trigger alarm when readings above/equal 5.9 °F

After 9 Consecutive violation readings (45 Minutes)

Trigger alarm when readings below/equal -40 °F

After 2 Accumulative violation readings (None)

Configure requires a password

Download requires a password

Advanced Options

< Back Next > Close Help

CHANGE THE LOGTAG BATTERY



LOGTAG DISPLAY SCREEN

- ▶ Pic #1 Observations?



LOGTAG DISPLAY SCREEN

- ▶ Pic #1 Observations?
- ▶ Current temperature is 46.4 de
- ▶ Alarm notification today
- ▶ Has been recording for 1 day
- ▶ Time is 3:53pm
- ▶ Battery is ok



LOGTAG DISPLAY SCREEN

- ▶ Pic #2 Observations?



LOGTAG DISPLAY SCREEN

- ▶ Pic #2 Observations?
- ▶ The LogTag was unplugged during a temperature reading.
 - ▶ This appears as -40 degrees on the downloaded graph.



LOGTAG DISPLAY SCREEN

- ▶ Pic #3 Observations?



LOGTAG DISPLAY SCREEN

- ▶ Pic #3 Observations?
- ▶ Has been recording for 28 days
- ▶ No current temperature
- ▶ The LogTag only holds 27 days of data and stops recording on the 28th day
- ▶ Alarm notification every day



LOGTAGS IN DEPOT SHIPMENTS

- ▶ Starting in November, all vaccine order shipments from the Vaccine Depot will contain a LogTag temperature monitoring device with a probe in a plastic vial of glass beads
 - ▶ No paper temperature markers
- ▶ New CDC requirements for the transportation and distribution of state-supplied vaccine



LOGTAGS IN DEPOT SHIPMENTS

- ▶ When you open your shipment at your facility:
 1. Look at the LogTag display screen to ensure that:
 - ▶ The current temperature is within 35-46 degrees Fahrenheit
 - ▶ The word “Alarm” does NOT appear on the display screen
 2. Press the “Stop” button to stop recording

LOGTAGS IN DEPOT SHIPMENTS



LOGTAGS IN DEPOT SHIPMENTS

3. Physically receive in your vaccine order
 - ▶ Ensure the contents of the box match the invoice
 - ▶ Store appropriately in storage unit
4. Download the LogTag graph
 - ▶ Click Next on the configuration screen to put the LogTag back in Ready Mode

LogTag

User ID:

LogTag battery: OK

Enable pre-start logging

Record readings continuously, overwrite oldest when memory full

Record readings so that:

Recordings recorded will span at least days

Number of readings to record maximum is 7777

Record a reading every Minutes

Begin recording after a delay of Minutes

Trigger alarm when readings above/equal °F

After Accumulative violation readings (None)

Trigger alarm when readings below/equal °F

After Accumulative violation readings (None)

Configure requires a password

Download requires a password

LOGTAGS IN DEPOT SHIPMENTS

5. If the word “Alarm” did NOT appear on the display screen
 - ▶ It is not required to email the shipment LogTag graph to the Vaccine Depot
 - ▶ Electronically receive in your vaccine order in VacTrAK



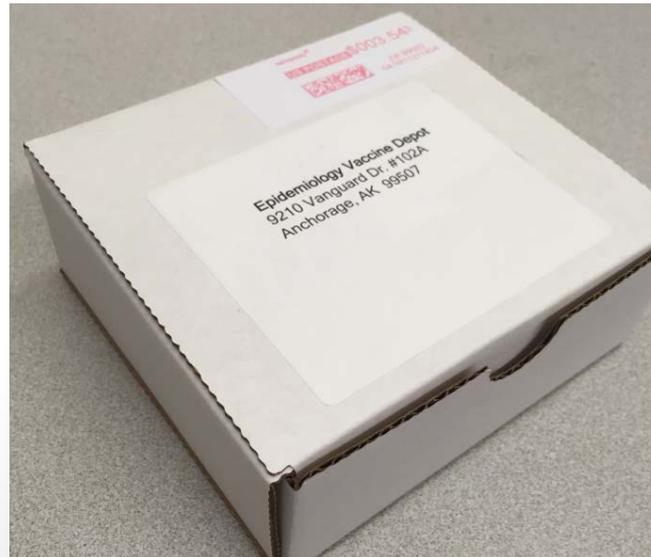
LOGTAGS IN DEPOT SHIPMENTS

5. If the word “Alarm” DID appear on the display screen:
 - ▶ Email the downloaded graph to the Vaccine Depot
 - ▶ Contact the Vaccine Depot for further instructions



LOGTAGS IN DEPOT SHIPMENTS

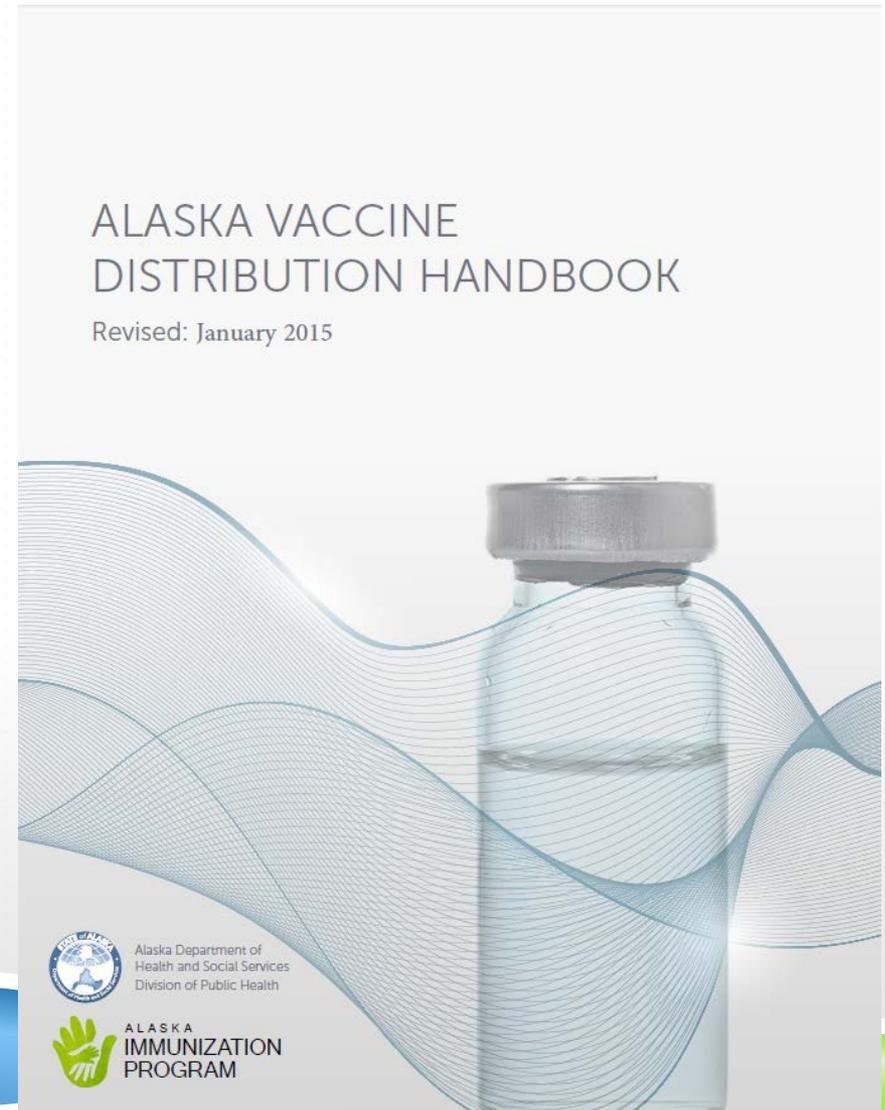
6. Place the LogTag device, vial and stand in the box provided to you
7. Place the box in the outgoing mail within one business day
 - ▶ Postage and Vaccine Depot address label will be on the box



- ▶ Future vaccine orders will be held until the LogTag is returned

VACCINE STORAGE AND HANDLING

- ▶ More vaccine storage and handling information and resources can be found:
 - ▶ In the Vaccine Distribution Handbook
 - ▶ On the State of Alaska Immunization Program website
 - ▶ Annual education webinar



Epidemiology

Public Health > Epidemiology > Immunization



ALASKA
IMMUNIZATION
PROGRAM



About Us

The mission of the Immunization Program is to prevent and control vaccine preventable disease in Alaska by:

- Providing vaccines to health care providers at no charge;
- Providing an immunization information system for use by health care providers and schools to maintain consolidated immunization records for Alaskans of all ages;
- Ensuring school and childcare compliance with immunization regulations;
- Providing immunization education and training for health care providers and the general public;
- Coordinating surveillance and control efforts for vaccine preventable diseases; and,
- Supporting efforts to increase vaccinations for all Alaskans

Programs and Activities

- » Resources for Parents and Patients
- » Resources for Health Care Providers
- » VacTrAK Immunization Information System
- » Vaccine Distribution Program
- » School and Child Care Immunization Compliance Program
- » Assessment, Feedback, Incentives, and eXchange Program (AFIX)
- » Perinatal Hepatitis B Case Management Program
- » Vaccine Preventable Disease Surveillance and Adverse Event Reporting

Spotlight

1 - 2 - 3 PROTECT ALASKA'S KIDS

HPV CANCER PREVENTION

[Click for more information](#)

Public notice on proposed State regulations changes related to immunizations

- » Division of Insurance: Determination of Final Payment for Covered Vaccine
- » 7 AAC 27.Preventive Medical Services
- »  Transcript of the Oral Hearing 2015-05-20

- » Immunization Information
- » VacTrAK
- » Vaccine Distribution Program
- » School & Child Care Immunization Requirements
- » AFIX
- » Perinatal Hepatitis B

Highlights

- » Conditions Reportable
- » Epidemiology Bulletins
- » Epidemiology Publications
- » Bibliography of Published Studies
- » Links of Interest
- » Epidemiology Contact List

Epidemiology Programs

- » Environmental Public Health
- » Health Impact Assessment
- » HIV & Sexually Transmitted Disease
- » Immunization
- » Infectious Diseases & Tuberculosis Control
- » Injury Surveillance

Public Health

- » Public Health Home
- » Certification & Licensing
- » Chronic Disease Prevention and Health Promotion

Epidemiology

Public Health > Epidemiology > Immunization > Vaccine Distribution



ALASKA
IMMUNIZATION
PROGRAM



Vaccine Distribution Program

Health care providers may enroll to receive VFC and/or state-supplied vaccine from the Alaska Immunization Program. In order to enroll, you must fill out and submit a VacTrAK Provider Application and a Vaccine Provider Agreement annually.

- » Vaccine Provider Agreement
-  Vaccine Provider Agreement Instructions
-  Directory of Providers Enrolled to Receive State-supplied Vaccine

Alaska Vaccine Distribution Handbook

-  Alaska Vaccine Distribution Handbook
- » "You Call the Shots" Webinar Training Required for Certifying Providers
-  Excerpts from CDC's Vaccines For Children Operations Guide

Eligibility Screening

-  2015 State-Supplied Vaccine Eligibility for Children *5/17/2015*
-  2015 State-Supplied Vaccine Eligibility for Adults *Updated 9/25/2015*
-  Patient Eligibility Screening Form *Updated 9/8/2015*

Vaccine Storage and Temperature Monitoring

-  2016 State-supplied Vaccine Storage Unit Type Requirements
-  Vaccine Temperature Log and Action Taken Form
-  Facility Incident Report Form
-  Emergency / Power Outage Plan for Vaccines (editable)
-  "Do Not Unplug" Signs
 - LogTag TRED
 -  LogTag Software and Device Initial Setup
 -  LogTag Instructions for Daily Use
 - VFC-6000 Data Logger
 -  Data Logger Setup
 -  Data Logger Download and Restart
 -  "Have You Checked the LED?" Sign

Transfer Form

-  State-Supplied Vaccine Transfer Form

- » Immunization Information
- » VacTrAK
- » Vaccine Distribution Program
- » School & Child Care Immunization Requirements
- » AFIX
- » Perinatal Hepatitis B

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Public Health

- » Public Health Home
- » Certification & Licensing
- » Chronic Disease Prevention and Health Promotion
- » Epidemiology
- » Injury Prevention & FMS

SITE VISITS

Lorraine Alfsen



SITE VISITS

- ▶ Purpose

- ▶ Education

- ▶ Includes, but is not limited to requirements regarding:

- ▶ Eligibility

- ▶ Billing

- ▶ Vaccine storage and handling

- ▶ VacTrAK

- ▶ Documentation

- ▶ Assess and provide feedback on provider activities and practices related to state-supplied vaccine

- ▶ Continuing process beginning with new enrollment visits and occurring throughout a provider's participation with Alaska's Vaccine Distribution Program

- ▶ In addition to required visits, providers and staff may request additional educational contacts