

Texas Department of State Health Services



Designing Around Consent: ImmTrac Replacement Project in Texas

AIRA 2015 National Meeting
April 22, 2015

Outline

- DSHS Immunization Branch
- ImmTrac Replacement Project
 - ImmTrac
 - EVI
- Consent in Texas
- Proposed ImmTrac Legislation
- Questions?

Texas DSHS

Immunization Branch

Vision:

- A Texas free of vaccine-preventable diseases

Mission:

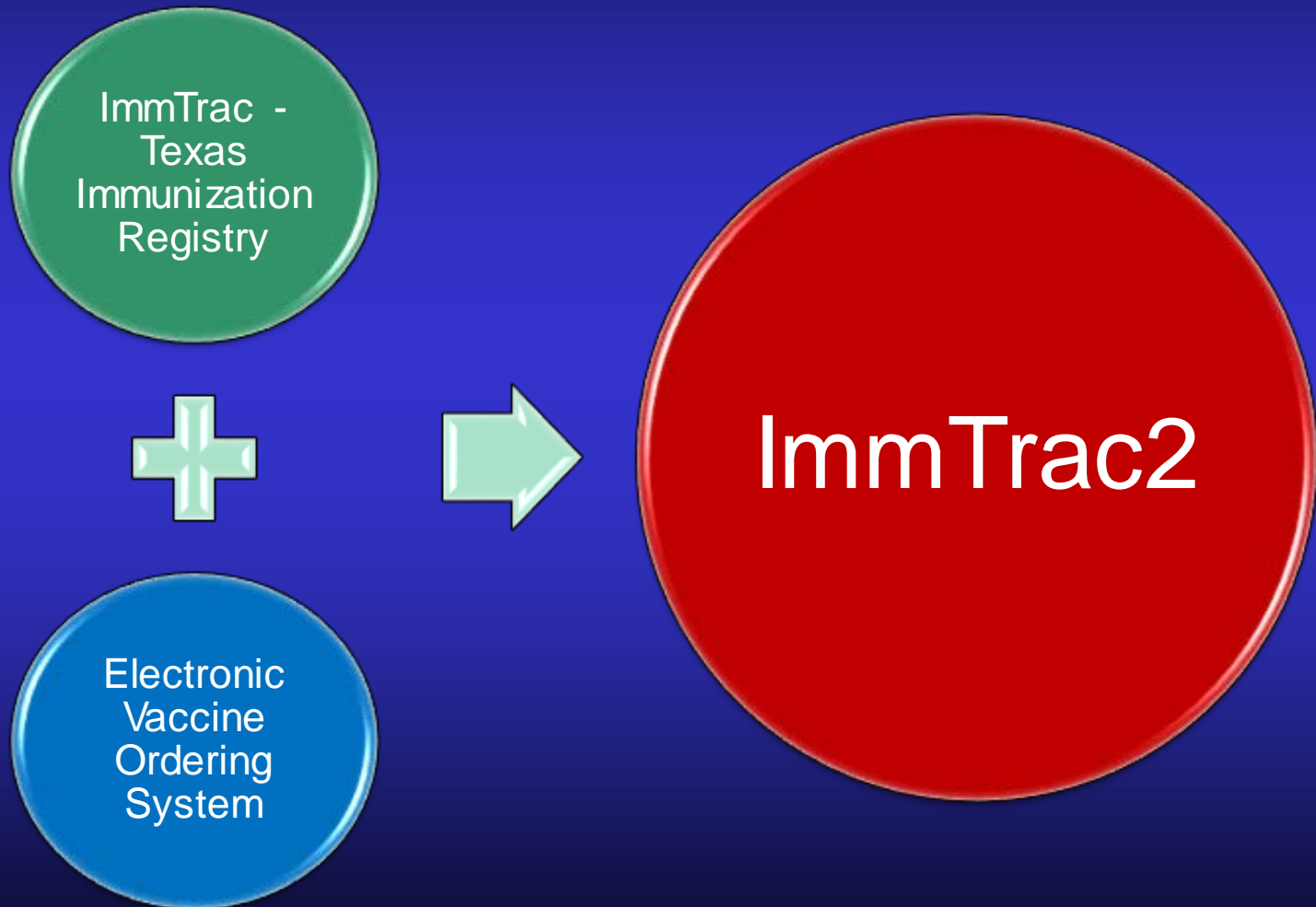
- To provide leadership to increase vaccine coverage levels and to reduce the burden of vaccine preventable diseases

Strategies to Increase Immunization Rates



- Promoting the Medical Home
- Developing and implementing systematic provider, public, and parent education
- Increasing access points of TVFC and Adult vaccinations
- Promoting the use of the Statewide Immunization Registry, ImmTrac

ImmTrac Replacement Project



ImmTrac System

- Texas House Bill No. 3054 in the 75th legislative session in 1995 called for the creation of the registry by 1997.
- 1995: DSHS began registering public medical providers to use the ImmTrac application
- 1996: the registry application was available for request by any private medical provider.
- Under Texas Health & Safety Code 161, has operated as an “opt-in” registry since 1999.

ImmTrac System

- Currently has over 131.2 million immunizations recorded
- 7 million children in the registry
 - 2.3 million under age 6 years
- 383,870 adults in the registry
- Approximately 11,000 active users

Electronic Vaccine Inventory (EVI) System

- Established in 2010
- EVI allows TVFC providers to record current inventory and place vaccine orders
- Provider submits order through EVI
 - DSHS transmits EVI orders to CDC
- Doses administered are recorded in aggregate

Electronic Vaccine Inventory (EVI) System

- Robust, fully functioning inventory management system
- 9,415,896 doses ordered through EVI in 2014
- 3,404 sites enrolled in TVFC

Consent in Texas

Consent Law

Sec. 161.007. IMMUNIZATION REGISTRY; REPORTS TO DEPARTMENT.

- (a) The department, for the primary purpose of establishing and maintaining a single repository of accurate, complete, and current immunization records to be used in aiding, coordinating, and promoting efficient and cost-effective communicable disease prevention and control efforts, shall establish and maintain an immunization registry.

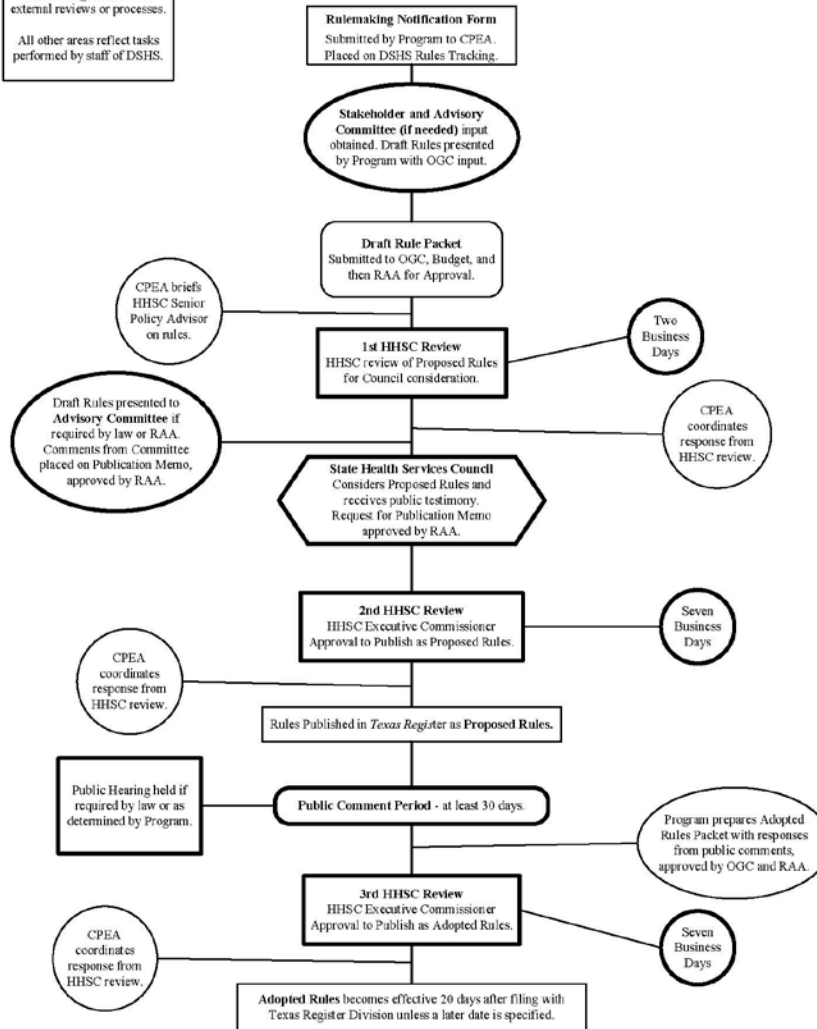
The executive commissioner of the Health and Human Services Commission by rule shall develop guidelines to:

- (1) protect the confidentiality of patients in accordance with Section 159.002, Occupations Code;
- (2) inform the individual or the individual's legally authorized representative about the registry and that registry information may be released under Section 161.00735;

- (3) require the written or electronic consent of the individual or the individual's legally authorized representative before any information relating to the individual is included in the registry;
- (4) permit the individual or the individual's legally authorized representative to withdraw consent for the individual to be included in the registry; and
- (5) determine the process by which consent is verified, including affirmation by a health care provider, birth registrar, regional health information exchange, or local immunization registry that consent has been obtained.

DSHS Rulemaking Process Flow Chart 3-1-11

Outlined figures indicate external reviews or processes.
All other areas reflect tasks performed by staff of DSHS.



Client Type	Attributes
ImmTrac Child	<ul style="list-style-type: none"> • This client is a child whose parent or legal guardian gave consent to retain their data in ImmTrac. • The client can be a first responder's minor family member.
ImmTrac Adult	<ul style="list-style-type: none"> • This client is an adult who gave consent to retain their data in ImmTrac; an adult's legal guardian can also give consent on the adult's behalf. • This is type of ImmTrac client was introduced by Senate Bill 346 in 2009.
First Responder (FR)	<ul style="list-style-type: none"> • This client acts as first responder in emergency events. • "View FR/FM" rights are required to view these clients.
Adult Family Member of a First Responder (FM)	<ul style="list-style-type: none"> • This client is an adult related to a first responder. • Children of first responders do not have a separate client type. Instead, they are added as an ImmTrac child (IC) with a Minor FR Family Member attribute. • "View FR/FM" rights are required to view these clients.

Client Type	Attributes
Pending Adult Consent (PA)	<ul style="list-style-type: none"> • This client is an adult between 18 and 19 years old for whom ImmTrac only has childhood consent on file. • Once a client turns 18, their childhood consent is no longer valid and they must give adult consent to remain in the registry.
Pending Verification (PV)	<ul style="list-style-type: none"> • This client does not have a valid client consent type on file. • The client could be an unconsented QM, or could have reached 19 years of age since the previous over age purge. • ImmTrac removes the unconsented QM clients that have reached their 90-day expiration, and all unconsented over age clients that are not associated with a disaster.
Disaster Related Client – (DC and DU)	<ul style="list-style-type: none"> • This client was administered an anti-viral, immunization, and/or medication as part of a regionally/nationally declared disaster. • The DC client gave consent to have their records retained beyond the disaster retention period. • The DU client did not give consent to have their records retained beyond the disaster retention period; however, ImmTrac is legally bound to retain their <i>disaster-related</i> information for a designated period of time. • “View Client Disaster” rights are required to view these clients

Methods of Capturing Consent

Data Exchange (Provider)	User Interface (Provider)	Direct from Client
Affirmation file <ul style="list-style-type: none"> Consent form may be saved at the provider level with either an electronic or wet signature 	I have a consent form on file. <ul style="list-style-type: none"> Consent may be saved at the provider level with either an electronic or wet signature 	Fax <ul style="list-style-type: none"> Form completed, signed and faxed by client to ImmTrac Group main fax
	I would like to print a consent form. <ul style="list-style-type: none"> Once form is signed, then affirm consent by using checkbox on screen 	Mail <ul style="list-style-type: none"> Form completed, signed and mailed by client to ImmTrac Group
Vital Statistics Unit Birth file <ul style="list-style-type: none"> All births certified through the Texas Electronic Registrar who have obtained consent from the parent/legal guardian 	I would like a consent form to pre-populate electronically based on information entered into the smart search fields. <ul style="list-style-type: none"> Once form is signed, then affirm consent by using checkbox on screen 	In Person <ul style="list-style-type: none"> Form completed, signed and presented by client to ImmTrac Group

Complexities of Consent

- 46 requirements related to consent
- Thus far, 16 FDDs related to consent management in the first design and development cycle.
 - Due to the intricacy, there were 12 additional addendums to the FDDs.

Designing around Consent

- Consent client types.
- Modifying the UI to record the capture of consent at the provider level.
- Capturing consent history for audit purposes.
 - Where, by whom, and when
- Questionable matches and the hierarchy of consent.
- Decrementing doses for unconsented individuals and dose-level accountability.
- Implementing consent viewing permissions at the user role level.

View Permissions

Org Types and Roles with the "View FRFM"

Roles by Org Types

Org Type	Num Users
College/University with DX	15
College/University with NO DX	336
College/University Non-Providers with NO DX	
Community Health Center with DX	16
Community Health Center with NO DX	1987
Community Health Center Non-Providers with NO DX	
Correctional Facility with NO DX	24
Correctional Facility Non-Providers with NO DX	
Daycare with NO DX	51
Daycare Non-Providers with NO DX	
Dialysis Center with DX	9
Dialysis Center with NO DX	85
Federally Qualified Health Clinic with DX	12
Federally Qualified Health Clinic with NO DX	952
Federally Qualified Health Clinic Non-Providers with NO DX	
Fire Dept - EMS with DX	3
Fire Dept - EMS with NO DX	67
Health Plans with DX	1
Health Plans with NO DX	1
Health Plans Non-Providers with DX	
Health Plans Non-Providers with NO DX	
Hospital with DX	36
Hospital with NO DX	1645
Hospital Non-Providers with DX	
Hospital Non-Providers with NO DX	
Local Health Dept with DX	23
Local Health Dept	

View.DisasterClients
Org Types and Roles with the "View Disaster-only Clients" right

Roles by Org Types

Org Type	Num Users		
College/University with DX	15		Fu
College/University with NO DX	336		Fu
College/University Non-Providers with NO DX		4	Vie
Community Health Center with DX	16		Fu
Community Health Center with NO DX	1987		Fu
Community Health Center Non-Providers with NO DX		39	Vie
Correctional Facility with NO DX	24		Fu
Correctional Facility Non-Providers with NO DX		4	Vie
Daycare with NO DX	51		Fu
Daycare Non-Providers with NO DX		7	Vie
Dialysis Center with DX	9		Fu
Dialysis Center with NO DX	85		Fu
Federally qualified Health Clinic with DX	12		Fu
Federally qualified Health Clinic with NO DX	952		Fu
Federally qualified Health Clinic Non-Providers with NO DX		24	Vie
Fire Dept - EMS with DX	3		Fu
Fire Dept - EMS with NO DX	67		Fu
Health Plans with DX	1		Fu
Health Plans with NO DX	1		Fu
Health Plans Non-Providers with DX		1	Vie
Health Plans Non-Providers with NO DX		5	Vie
Hospital with DX	36		Fu
Hospital with NO DX	1645		Fu
Hospital Non-Providers with DX		1	Vie
Hospital Non-Providers with NO DX		31	Vie
Local Health Dept with DX	23		Fu
Local Health Dept			Fu

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Texas Administrative Code

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Texas Administrative Code

TITLE 25

PART 1

CHAPTER 100

RULE §100.4

HEALTH SERVICES

DEPARTMENT OF STATE HEALTH SERVICES

IMMUNIZATION REGISTRY

Registry Consent and Withdrawal Relating to a Minor

(a) A parent, managing conservator or legal guardian of a patient younger than 18 years of age may consent to the inclusion of the child's immunization history in the immunization registry by doing one of the following:

(1) indicating consent at birth certificate registration, including by electronic signature;

(2) submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Department of State Health Services, Immunization Branch, MC-1946, P.O. Box 149347, Austin, Texas 78714-9347, or by courier to Department of State Health Services, Immunization Branch, 1100 West 49th Street, MC-1946, Austin, Texas 78756, or by calling the Immunization Branch at (800) 252-9152 to request a consent form:

(3) completing written consent to be submitted to a health care provider, birth registrar, regional health information exchange, or local immunization registry, who may review that consent and affirm that consent has been obtained via an affirmation process as directed by the department.

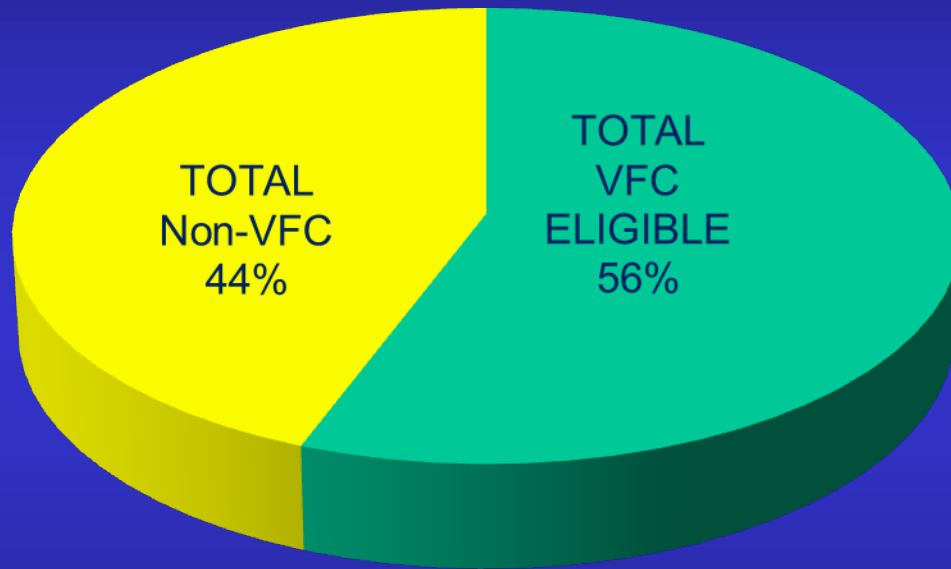
(b) Unless otherwise provided by §100.7 of this title (relating to Potential and Declared Disasters, Public Health Emergency, Terrorist Attack, Hostile Military or Paramilitary Action, and Extraordinary Law Enforcement Emergency Event), the department shall verify consent before including the reported information regarding the child in the immunization registry. Under Health and Safety Code, §161.007(a)(5), the department may elect to verify consent by receiving affirmation from a health care provider, birth registrar, regional health information exchange, or local immunization registry that consent has been obtained. The department shall provide notice to a provider that submits data elements for a person for whom consent cannot be verified. The notice shall contain instructions for obtaining and affirming consent and resubmitting the data elements to the department.

(c) Consent is required to be obtained only one time, and is valid until the child becomes 18 years of age, unless the consent is withdrawn in writing.

(d) A parent, managing conservator or legal guardian of a patient younger than 18 years of age may withdraw consent for the child to be included in the registry at any time by submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Department of State Health Services, Immunization Branch, MC-1946, P.O. Box 149347, Austin, Texas 78714-9347, or by courier to Department of State Health Services, Immunization Branch, 1100 West 49th Street, MC-1946, Austin, Texas 78756, or by calling the Immunization Branch at (800) 252-9152 to request a consent withdrawal form. Unless otherwise provided by §100.7 of this title, the department shall remove information from the immunization registry for any person for whom consent has been withdrawn, and the department shall send the parent, managing conservator or legal guardian a written confirmation of the removal of the information. The department may not retain individually identifiable information about any person for whom consent has been withdrawn except as provided for by §100.7 of this title.

Texas Childhood Population – 2015

(ages 0-18 years)



VFC Eligible:

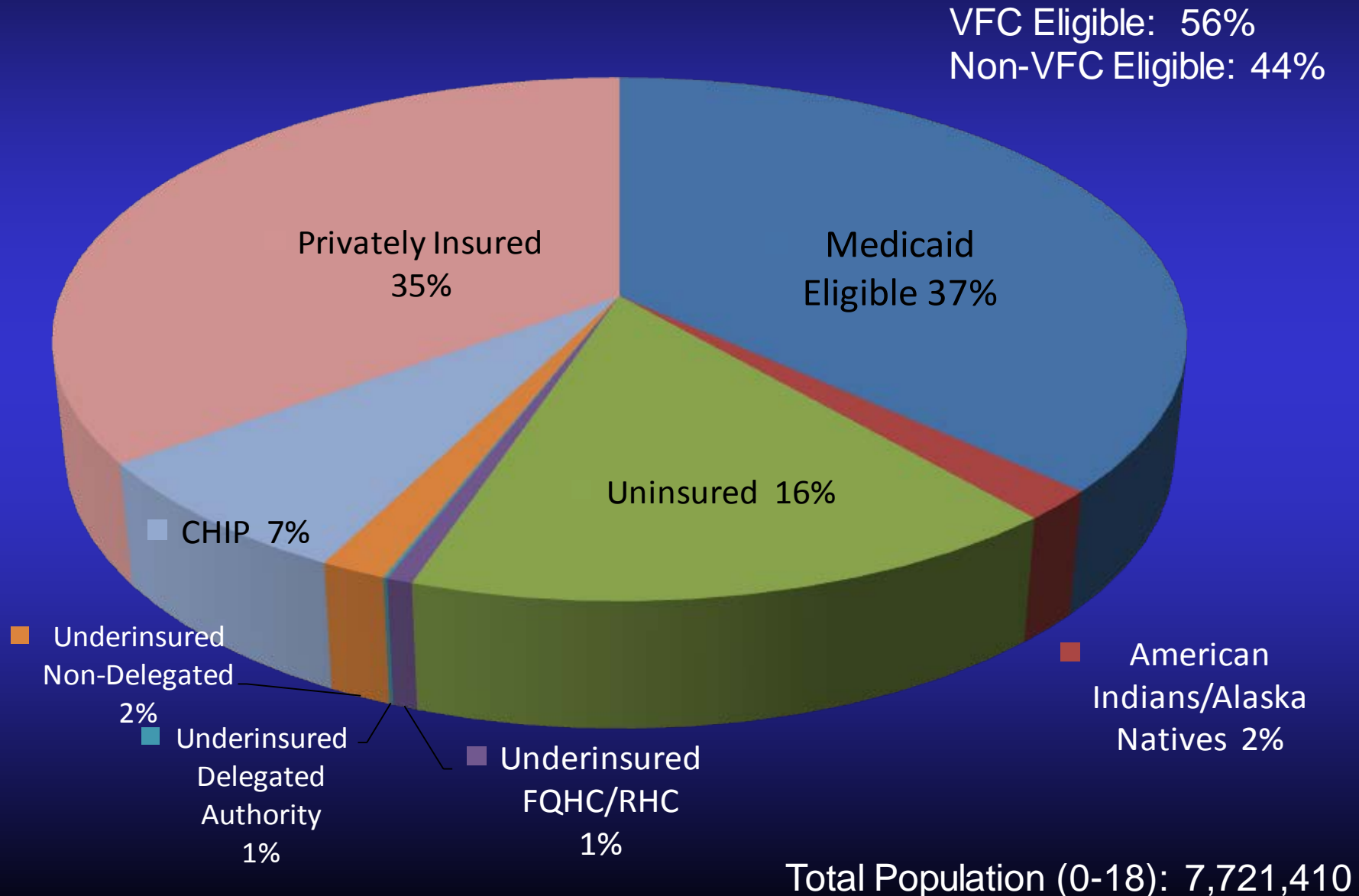
- Medicaid-eligible
- Uninsured
- American Indian/ Alaska Native
- Underinsured
 - has commercial (private) health insurance but coverage does not include vaccines; insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or vaccine coverage is capped at a certain amount (VFC eligible after cap is reached).

Non-VFC Eligible:

- Insured
- CHIP
- Underinsured in private sites

Total Population (0-18): 7,721,410

Texas 2015 Total Population (0-18) By Eligibility



2015 Texas Legislative Session

- House Bill 465 and Senate Bill 29 change ImmTrac from an opt-in registry to an opt-out.
- House Bill 2171 extends the timeframe for inclusion in the registry from 18 to 26 years of age.
- House Bills 2641 and 1319 relate to information authorized through a health information exchange.

Questions?

Kelly Patson

Kelly.Patson@dshs.texas.gov

Meredith Sugarman, MPH

Meredith.Sugarman@dshs.texas.gov

Tamara Lewis, MPH

Tamara.Lewis@dshs.texas.gov