

Registry Consent and Electronic Affirmation

Script

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Title

Today, we will be discussing Registry Consent and Electronic Affirmation for the Texas Immunization Registry.

Introduction

Hello everyone. My name is Jonathan Patterson. I will be your main presenter today. I am a Interface Analyst with the Texas Immunization Registry.

I am joined today by [Name], [Title] with the Texas Immunization Registry.

For this presentation, if you have any questions, you will see the option for submitting questions at the bottom of your screen. Please submit your questions there and we will address and answer those questions once the presentation is complete.

Overview

The topics we will cover include:

- Registry consent and Affirmation,
- Types of Consent,
- Withdrawal of consent,
- Manual Affirmation,
- Methods of Electronic Affirmation, and
- The importance of consent affirmation to providers.

Terminology

We will be using abbreviations and acronyms for some of the terminology in this presentation:

- Bi-D-X will be short for Bidirectional data exchange,
- F-T-P will be short for File Transfer Protocol,
- Registry will be used for the Texas Immunization Registry,
- Orgs will mean any provider, healthcare entity, or other organization that participates with the registry, and
- EHR will be used for Electronic Health Records systems or other similar records programs.

Registry Consent

Let's begin with an overview of registry consent.

Registry Consent Overview

What is registry consent?

Registry consent is a unique form of consent specific to the Texas Immunization Registry. It is different from other forms of consent such as the "consent to share or disclose" used by many organizations when following HIPAA guidelines.

Registry consent is required by the Texas Administrative Code. This makes the Texas Immunization Registry an opt-in only registry. Participation in the registry is entirely optional for your patients.

Patients (through their legal guardian) must give their consent once as a minor to have their records stored in the registry

After turning 18, patients have until their 26th birthday to give consent again as an adult if they want to keep their records in the registry. Patients may still grant consent after their 26th birthday, but any previous records from when they were a minor will be lost.

It's important to be aware that consent applies to the person, NOT to the organization that collected it. This means that once an organization affirms a person's registry consent ALL providers throughout the state of Texas may submit and request immunization records for that person without any

additional registry consent. However, providers must still follow all other applicable privacy laws.

Legislation

Let's briefly cover the laws that create the requirement for immunization registry consent in Texas.

Texas House Bill 2641 requires all Health and Human Services information systems that are implemented after September first, 2015 and exchange information with healthcare providers to use appropriate data standards.

ImmTrac2 predates this requirement but uses the national standard for sending and receiving immunization records called Health Level Seven, or HL7. HL7 does not currently support the reporting of Texas' unique registry consent by default.

However, the registry must also comply with an additional set of requirements created by the Texas Administrative Code, or TAC. The TAC establishes the requirement that individuals or their legal guardians must grant their consent to have records stored in the Texas Immunization Registry.

The TAC creates several different forms of consent:

- Subsection 100.4 establishes consent for minors. This requirement was later extended to adults when the registry became a lifetime registry.
- Subsection 100.7 establishes consent for disaster related immunizations. And,
- Subsection 100.8 establishes consent for first responders and their immediate family members.

Each of these is a unique form of registry consent today.

Non-consented Patients

Because of these laws, the registry must reject all records for non-consented patients. These means that those records will not be available in ImmTrac2. If you've ever noticed that some of your patients are missing from the registry, it's probably because the registry doesn't have that patient's consent. You can assist the registry and other providers that see your patients by screening for and capturing a patient's registry consent.

The only exception to the consent rule is for disaster related immunizations and antivirals.

During a declared disaster, the registry is required by the Texas Administrative Code to store all disaster related Antiviral and Immunization Medications records (AIMs for short) for five years even if no consent is on file.

Types of Registry Consent

Each type of registry consent has its own consent form. Today, we cover the three types of registry consent forms used by provider organizations the most often.

The Minor Consent form allows parents and legal guardians to grant consent for the registry to retain all immunization records for a minor until their 18th birthday.

The Adult Consent form allows an adult to grant consent for the registry to retain all their immunization records for their full lifetime.

Disaster consent is a bit different. As I mentioned earlier, the registry is required to keep disaster related records for five years without any form of consent. The Disaster Consent form allows the registry to retain those disaster related records indefinitely.

All of these forms can be found on the registry's forms page.

Affirmation

What is Affirmation?

Affirmation is the process of organizations notifying the registry of a person's signed registry consent form. Affirmation allows the registry to create a profile and begin accepting immunization records for that person.

This can either be done online via the ImmTrac2 website or electronically using your electronic health records (or EHR) system.

Withdrawal of Consent

It's important that we also discuss withdrawal of registry consent.

Texas law grants patients the right to withdraw their registry consent at any time by contacting the Texas Immunization Registry.

Those requests must be sent in writing to the registry. The registry provides and official withdrawal form on our forms page for this purpose.

When a person is withdrawn from the registry ALL record of that person is removed entirely. Not even the withdrawal request is saved. The withdrawal form is returned to the person along with a letter confirming that the registry has destroyed their records.

Patients are asked to inform their providers, but this is done at their own discretion. The patient does not have to inform anyone that they have withdrawn their consent.

Important Note

Withdrawal is the primary reason that consent should only ever be affirmed once when the patient first signs a registry consent form.

Consent should NOT be sent with every immunization records because that risks reaffirming a patient that has withdrawn.

Reaffirming a patient that has withdrawn without a new sign consent is a violation of Texas law.

Manual Affirmation

Now that everyone knows what registry consent is, lets talk about affirmation. This first method of affirmation we'll review today is Manual Affirmation.

What is Manual Affirmation?

Manual affirmation is simply the process of adding patients to the registry as clients using the ImmTrac2 website.

Manual affirmation is the same process you likely used prior to setting up data exchange.

It's also the method of affirmation most providers choose to use with FTP data exchange.

Unfortunately, Manual Affirmations is not an option for sites looking to participate in bidirectional data exchange.

This is because bidirectional data exchange happens in real time leaving no time for anyone to add the patient to ImmTrac2 manually.

Log in to ImmTrac2

To affirm consent for a patient manually, you will begin by logging in to the ImmTrac2 website.

If you have multiple org codes, be sure to log in using the one for the site that received the consent form.

This is important because whichever site you are logged in under will receive credit for the affirmation.

Enter New Client

Next, click the 'enter new client' button in the menu on the left-hand side of the window,

Smart Search

Fill out all of the patient's information,
and then click the 'Find' button on the right.

Add A Client

ImmTrac2 will then try to find any matching clients already in the registry

Review the list to see if your patient is already a client. If you find your patient, then stop. The patient already has consent on file and you do not need to add a new one.

If your patient wasn't in the list, then click 'Add a client',

And 'Submit'.

Client Information

You'll then be taken to the Client Page where you can add any additional information you might have for the patient.

Once you're done, click 'Continue Add'.

Client Summary

On the next screen you'll see the Client Summary.

If everything looks correct, click 'Continue'.

Affirm Consent

Finally, you'll select the they of consent the patient signed.

The options available on this last page are based on the patients age.

Once you're ready, click Affirm to add the patient to the registry.

The patient is now a consented registry client!

Manual Affirmation Overview

You should try to affirm consent soon after receiving the signed consent (ideally within less than 24 hours). This helps ensure that no records sent through FTP data exchange are rejected because the consent wasn't affirmed soon enough.

A more detailed description of this process can be found in our ImmTrac2 training videos online.

Electronic Affirmation

Now let's go over Electronic Affirmation.

What Is Electronic Affirmation?

What is Electronic Affirmation and how is it different?

Electronic affirmation is the process of affirming consent using a data exchange connection, much like how immunization records are sent electronically, without anyone logging in the ImmTrac2 website to add information manually.

Methods of Electronic Affirmation

Now that we've explained what registry consent is, let's talk about how electronic affirmation works.

The registry offers two different methods of electronic affirmation:

Affirmation files, and

HL7 Affirmation

Both types of electronic affirmation use the same interface your use to send AIMs.

That means FTP site will send affirmations through their FTP account and Bidirectional sites will send them through their Webservices connection.

Methods of Electronic Affirmation (*continued*)

Electronic affirmation is strongly encouraged for your organization to participate in Bidirectional Data Exchange with the registry. Your organization should choose and be ready to use one of these methods if you plan to use Bi-D-X.

With electronic affirmation, your organization would collect patients' signed registry consent as usual, but you would need a way of documenting that consent electronically. This could mean either documenting that consent was signed or actually collecting the patient's signature electronically.

As always, you would continue to keep the original signed consent with the patient's records.

Affirmation Files

The first method of electronic affirmation we'll cover are Affirmation Files.

Affirmation files, often called Affirmation Flat Files or simply Flat Files, are a type of simple text file used to send all of the necessary information about a patient and their consent to affirm them with the registry.

For those of you familiar with HL7, Affirmation files do NOT use HL7 formatting. Instead, they use precise spacing to format the information in the file.

Affirmation files were originally designed for providers to use with the unidirectional FTP batch file interface, so many providers already use Affirmation files.

With the bidirectional upgrade, providers can now send affirmation files using the real time webservices interface as well.

Keep in mind though that, because affirmation files are not HL7 messages, they must be sent separately from the patients Antiviral, Immunization, and other Medication records.

This leads to the most significant caveat of using affirmation files. They must be sent well before any immunization records so that the registry has time to create an account for that patient before any immunization records can be added to it.

Affirmation File Specifications

The specifications for creating affirmation files are covered in the Electronic Standards for Affirmation of Registry Consent, which is available on our forms webpage. This is the document you would want to share with your EHR vendor or other IT support.

Affirmation Files are limited to three types of consent. The codes for consent are:

- 'A' for adult consent,
- 'Y' for minor consent, and
- 'D' for disaster consent.

HL7 Affirmation

The second and newest option we'll cover is HL7 Affirmation.

HL7 affirmation uses a unique set of codes developed for the Texas Immunization registry to

Send affirmation information within your immunization messages.

With this method you wouldn't need to develop any new file formats or send separate messages to the registry just for affirmation. All message types including immunization record updates, history requests and consent affirmation, would use the same interface.

There wouldn't be any timing issues between affirmation and reporting immunizations because all the information could be in the same message.

The most significant challenge with HL7 affirmation is EHR compatibility. Most EHRs need special setup and upgrades to support HL7 affirmation. Texas' consent requirements are different from any other state's so most EHRs are not yet capable of sending this type of consent information in HL7 messages.

Changes for HL7 Affirmation

The specifications for HL7 consent are covered in the *Affirmation of Registry Consent via Health Level Seven Guide*.

HL7 affirmation requires a few unique changes to your HL7 messages that differ from the regular specifications. Don't worry if you don't understand the

information we're about to cover. All of this covered in the guide, which should be shared with your EHR vendor.

MSH-22 must contain the affirming site's TX IIS ID number. The affirming site is the site that collected the signed consent.

This information should match RXA-11.4 if it's included in a VXU message.

PD1-12 must use one of the registry's unique codes for the type of registry consent being reported. We'll cover the full list of codes on the next slide.

The Y and N codes normally used in PD1-12 are not used by the registry for consent.

PD1-13 must contain the date registry consent was signed.

HL7 Consent Codes

The unique code used by the registry for consent in PD1-12 include:

- TXY for a regular minor consent,
- TXA for a regular adult consent, and
- TXD for a disaster consent.

When to Transmit Records

With all the different types of consent and ways to send affirmation electronically, it can sometimes feel overwhelming deciding when to report immunizations to the registry.

Fortunately, the answer is simple; immunization records should ALWAYS be sent to the registry regardless of whether patient signs a registry consent form or granted consent to share their records with others.

Public health registries like the Texas Immunization Registry are exempt from consent to share laws, so consent to share is not a consideration for reporting to the registry.

The registry also reviews each patient for registry consent before determining whether to retain or reject records. It is not your responsibility to determine if your patients have registry consent before reporting immunizations electronically. You are only required to report consent when you receive a new signed registry consent from your patient.

Improvements for Providers

Let's wrap up by highlighting a few of the benefits of electronic affirmation for providers.

Electronic affirmation significantly improves immunization record acceptance rates, which will show on the TIPS reports.

This leads to more complete and accurate patient records in the registry and improves continuity of care.

Electronic affirmation also improves provider workflows by removing the need to process consents manually on the ImmTrac2 website.

Resources

Finally, here are some of the resources available to you from the registry.

Resource Guides

Related resource guides include:

- The Electronic Data Exchange Resource Guide, stock number 11-15231, which provides detailed steps and information on how to establish a data exchange connection with the registry.
- The Informational Guide on Bidirectional Data Exchange, stock number #11-15957, describes the process of establishing and maintaining a bidirectional data exchange connection with the registry.
- The Texas Immunization Registry Consent Overview, stock number 11-15702, provides information about what registry consent is and how it works. This is a non-technical document that non-IT individuals can easily read and answers most common questions about consent.
- The *Electronic Standards for Affirmation of Registry Consent*, stock number E11-13415, covers the specifications for affirmation flat files. And,
- The *Affirmation of Registry Consent via Health Level Seven*, stock number 11-15773, covers the specifications for affirmation via HL7.

All these documents and more can be found on our forms page at www.dshs.texas.gov/immunize/immtrac/forms.shtm

Email

You can request support by emailing the Texas Immunization Registry. The registry has two email addresses.

Email us at ImmTrac2@dshs.Texas.gov for questions about ImmTrac2 access, site registrations or renewals, adding or removing users, training, or publications.

Email us at ImmTracMU@dshs.Texas.gov for questions on data exchange, promoting interoperability, or data quality reports.

Thank you!

This concludes our presentation.

Thank you very much for your time.

In the next presentation we will be covering the bidirectional data exchange testing.

Q & A

We'll now begin our Q&A session.