

# **Texas Immunization Registry: Affirmation of Registry Consent via Heath Level Seven**

## **Overview**

To assist health care providers to report immunization data and registry consent via data exchange, the Texas Immunization Registry enhanced its system, ImmTrac2, to capture registry consent via Health Level Seven (HL7). This enhancement allows for the sending of immunization data and registry consent together via HL7.

This enhancement alleviates the burden on providers and their staff using manual entry processes or multiple data exchange file types. Currently, providers report an individual's consent to the registry via manual entry in ImmTrac2 or through data exchange using a flat file (non-HL7) known as an affirmation of registry consent file.

## **Purpose**

This document will assist providers and their electronic health records (EHR) support to identify the program rules, state requirements and HL7 standards required to report registry consent via HL7.

## **Patient Demographic (PD1) Segment**

PD1 Segment, specifically PD1-12, captures whether an individual's information can be shared with others and identifies the protection indicator for their data. This information is documented in electronic health records (EHR) systems. When the protection indicators are sent via HL7, it signifies to the receiving registry whether to protect or not protect the data.

## Protection Indicators

- Y - Yes, protect the data. Patient (or legal guardian) has indicated that the information must be protected. Do not share the data.
- N - No, do not protect the data. Patient (or legal guardian) has indicated that the information does not need to be protected. Data can be shared.
- Blank.

Example of PD1 Segment with Protection Indicators included:

PD1|||||||Y|20200105

## Use of Protection Indicators

Most states use these protection indicators, when populated in PD1-12, to identify registry consent and determine whether a registry record for the patient is created.

***In Texas, these protection indicators are not used to create a registry record. The protection indicators are ignored by the registry.***

Due to Texas' registry consent laws<sup>1</sup>, the patient must provide their written consent to be a registry client using an official Texas Department of State Health Services (DSHS) consent form. The DSHS consent forms (also known as registry consent forms) are unique and separate from the forms used to capture a patient's consent to share or protect their information.

## Registry Consent

To differentiate between the protection indicators, the registry uses unique registry consent values to capture when a patient (or the parent or legal guardian) has given their written consent to the registry by signing a registry consent form.

These unique registry consent values are:

- **Code: TXD**
  - Description: An individual (all ages) who signed the Immunization Registry (ImmTrac2) Disaster Information Retention Consent Form (Stock # F11-12956).
  - The client type created is Disaster Consented.

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<sup>1</sup> Texas Health and Safety Code, Section 161.007

- **Code: TXY**

- Description: An individual younger than 18 year of age whose parent or legal guardian signed the Immunization Registry (ImmTrac2) - Minor Consent Form (Stock # C-7).
- The client type created is ImmTrac Child.

- **Code: TXA**

- Description: An individual 18 years of age or older who signed the Immunization Registry (ImmTrac2) - Adult Consent Form (Stock # EF11-13366).
- The client type created is ImmTrac Adult.

Not all EHR systems or vendors are able to differentiate the protection indicators from registry consent when sending data to the registry. This can result in a patient being added as a registry client without proper written registry consent as required by state law.

## Requirements for Affirmation of Registry Consent via HL7

Immunization information (VXU) does not require affirmation of registry consent to be included, and if it is not included, the VXU will process as it normal (if error free).

### **MSH-22**

- Required.
  - Refer to **Table 1: Data Sent to the Registry** for more information.
- Captures the TX IIS ID of the organization that has the signed registry consent form on file.
  - Also known as the affirmer or affirming organization.
  - Must contain a valid TX IIS ID, either of submitting organization or of one of its sub-sites.

### **PD1-12**

- Required only when sending affirmation of consent data.
- Captures the registry consent value for the patient, based on the registry consent form the patient signed.
  - The registry consent form must be appropriate for the patient's age.

- TXD is not age-specific, so no age-related requirements exist.
- If value is TXY, then the current date must be less than 18 years after the patient's birth date.
  - Example: The current date is July 27, 2020, and the patient's birthday is July 1, 2019. If value is TXA, then the current date must be 18 years or more after the patient's birth date.
  - Example: The current date is July 27, 2020, and the patient's birthday is July 1, 1984.

**PD1-13**

- Required only when sending affirmation of consent data in PD1-12.
- Captures the date the registry consent was signed by the individual or the individual's legal guardian.
  - Also known as the affirmation date.
  - Date format – YYYYMMDD
    - Example: 20191110
    - Date cannot be in the future, nor before the patient's date of birth.

**Other Requirements**

- If an HL7 message contains immunizations and affirmation of registry consent that result in the affirmation of consent having a data quality error, the entire HL7 message is rejected.
  - This means both the immunization and registry consent are rejected. The immunization error must be resolved.
  - The affirmation of consent and immunization information must be resent to add the patient as a registry client and report the immunization.
- Due to state law regarding withdrawal of registry consent<sup>2</sup>, DSHS cannot retain any records of an individual's history in the registry (i.e., previous consent history).

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<sup>2</sup> Texas Administrative Code (TAC), Rules §100.4; Texas Health and Safety Code, Section 161.007

- Registry of consent must be sent only once at the time it was obtained, not stored as historical and sent at every occurrence of reporting immunizations or data.
  - This ensures state law is adhered to if an individual withdraws themselves from the registry.
  - If the organization resends a previous registry consent, after the individual has removed themselves, the registry creates a new record for the individual without proper consent. This is noncompliant with state law and a violation of patient information.
  - To ensure the proper registry consent is sent, we recommend providers screen patients for registry consent at each visit. This allows the organization to obtain a current and accurate registry consent response from the patient.
  - If the patient consents to the registry at the time they are screened, and the provider reports the registry consent accurately to the registry, it must be associated to a true, current, and signed registry consent form from the patient.

Example of MSH and PD1 Segment with registry consent fields included:

```
MSH|^~\&|EPIC|1234567890|TxImmTrac|TxDSHS|20200720083345|P70925|VXU
^V04^VXU_V04|4032184|P|2.5.1|||AL|AL|||||1124390005|
PID|1||E3752611^^^EPIC^PI||ESCAPE^ARTIST||20191223085900|M|LOPEZ
TRAPEZA|2106-3^White|123 MAIN CIRCLE^^BALCH
SPRINGS^TX^75180^US^^^TX113|||||||||||||
PD1|||||||||TXY|20200105
```

## HL7 Data Sent to the Registry

To determine what data should be sent to the registry, refer to the Table 1 below that indicates:

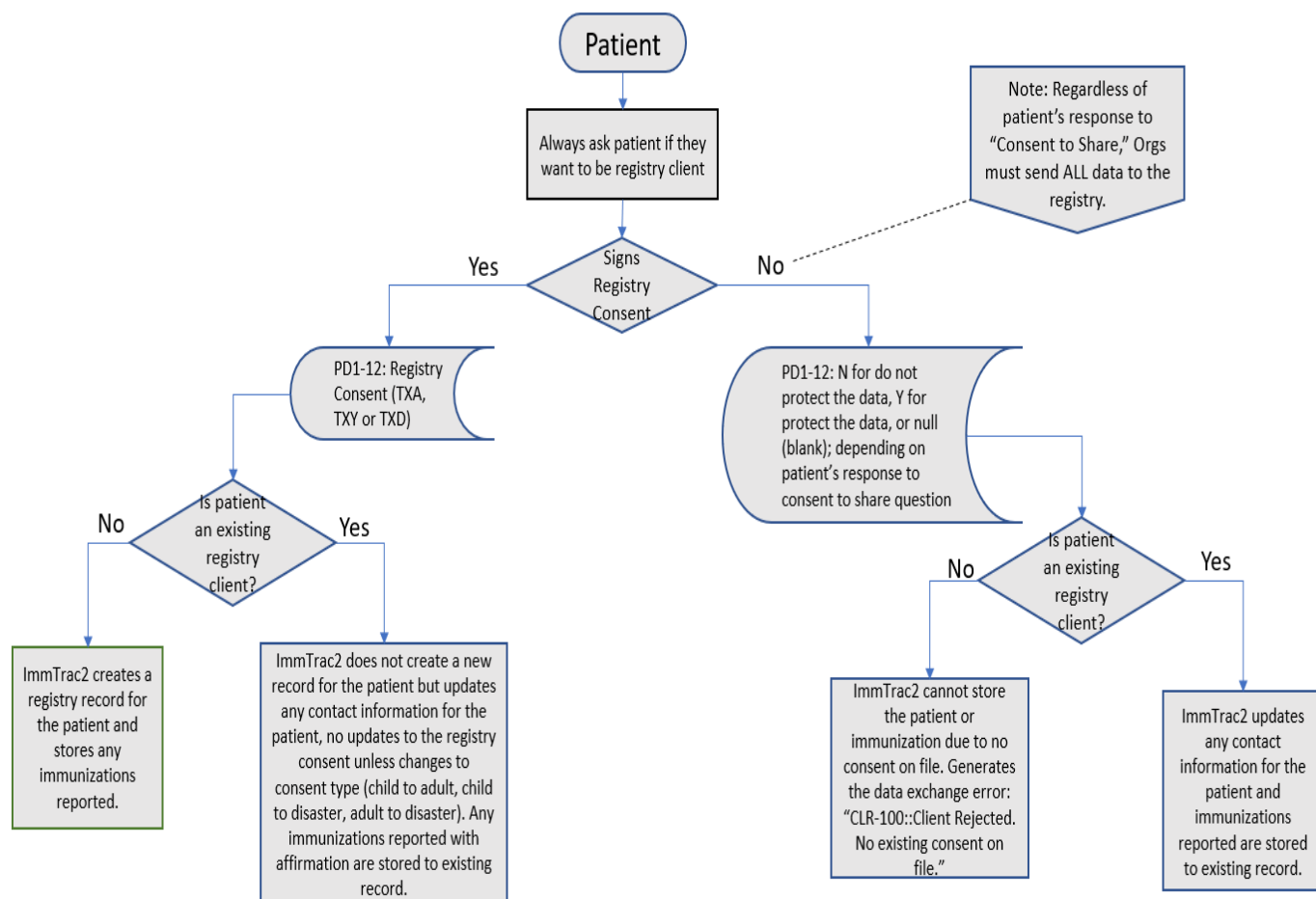
- All immunization data, regardless of a patient's consent to share or registry consent, must be sent to the registry.<sup>3</sup>
- Scenarios in which a patient does or does not sign an ImmTrac2 registry consent form, does or does not consent to the "Consent to Share" data, and what the specifications are for HL7 fields for each scenario.

<sup>3</sup> TAC, Rules §100.6 and §100.8; Texas Health and Safety Code, Section 161.007

**Table 1: Data Sent to the Registry**

<b>Patient does...</b>	<b>and their response to the "consent to share" question is...</b>	<b>Then send their data to the registry with these HL7 configurations...</b>	<b>The expected outcome is...</b>
NOT sign an official ImmTrac2 Consent Form.	No, don't share my data.	MSH-22: Is dependent on the type of data exchange being used: <ul style="list-style-type: none"> <li>• Unidirectional (FTP/SFTP) - Blank, not required.</li> <li>• Bidirectional (Web Services) - Required, TX IIS ID of site reporting or querying.</li> </ul> PD1-12: Y for protect the data. PD1-13: YYYYMMDD for the date of response to the consent to share question.	Immunizations are stored only if the patient is an existing registry client and their registry consent is already on file.
NOT sign an official ImmTrac2 Consent Form.	Yes, share my data.	MSH-22: Same as above. PD1-12: N for do not protect the data. PD1-13: Same as above.	Immunizations are stored only if the patient is an existing registry client and their registry consent is already on file.
Sign an official ImmTrac2 Consent Form.	No, don't share my data.	MSH-22: Required, TX IIS ID of site affirming the registry consent is on file with them. PD1-12: Appropriate Registry Consent Value (TXA...TXD). PD1-13: YYYYMMDD for the date the registry consent form was signed.	A registry record is created for the patient and the immunizations reported are stored in their record.
Sign an official ImmTrac2 Consent Form.	Yes, share my data.	MSH-22: Same as above. PD1-12: Same as above. PD1-13: Same as above.	A registry record is created for the patient and the immunizations reported are stored in their record.

## PD1-12 Registry Consent Flow Chart



*Figure 1 - PD1-12 Registry Consent Flowchart*

## ***Accessible Version of PD1-12 Registry Consent Flowchart***

The provider first asks the patient if they want to be a Texas Immunization Client and sign a registry consent.

1. If **"Yes"** to **"Did the patient sign a registry consent form?"** then for PD1-12 use TXA for adult consent, or TXY for minor consent, or TXD for disaster consent. This information is reported via electronic data exchange.

When the data is accepted and processed by ImmTrac2, ImmTrac2 will identify **"Is patient an existing registry client?"**

- a. If **"Yes"** to **"Is patient an existing registry client?"**, then ImmTrac2 does not create a new record for the patient but updates any contact information for the patient. No updates are made to the registry consent unless there is a change to consent type (child to adult, child to disaster, adult to disaster). Any immunizations reported with the affirmation are stored to the existing registry record. Stop.
  - b. If **"No"** to **"Is patient an existing registry client?"**, then ImmTrac2 creates a registry record for the patient and stores any immunizations reported. Stop.
2. If **"No"** to **"Did the patient sign a registry consent form?"**, then for PD1-12 use N for "do not protect the data", Y for "protect the data", or null (blank); depending on patient's response to Consent to Share question.

**NOTE:** Regardless of patient's response to "Consent to Share", organizations must send ALL data to the registry.

When the data is accepted and processed by ImmTrac2, ImmTrac2 will identify **Is patient an existing registry client?**

- a. If **"Yes"** to **"Is patient an existing registry client?"**, then ImmTrac2 updates any contact information for the patient and immunizations reported are stored to the existing record. Stop.
- b. If **"No"** to **"Is patient an existing registry client?"**, then ImmTrac2 cannot store the patient or immunization due to no consent on file. A data exchange error is generated: "CLR-100::Client Rejected. No existing consent on file." Stop.



## Implementing Registry Consent via HL7

As this is a new functionality, the registry requires health care providers and their EHR vendors to contact the Interoperability Team to discuss testing options available and next steps in the implementation process.

Health care providers must establish, implement, and maintain appropriate procedural, administrative, physical and technical safeguards to ensure that only individuals who have signed a DSHS official registry consent form are affirmed to the Texas Immunization Registry. Health care providers are responsible for the accuracy of affirmation submissions to the registry.

## Resources

For additional content related to registry consent and data exchange (HL7) specifications refer to the below resource that are available on our DSHS [website](#):

- Texas Immunization Registry – Consent Overview, stock # 11-15702.
- Texas Immunization Registry HL7 2.5.1 Implementation Guide, stock # 11-14972.

## Registry Contact

For more information and support contact the Texas Immunization Registry Interoperability Team.

Email: [ImmTracMU@dshs.texas.gov](mailto:ImmTracMU@dshs.texas.gov)

Phone: 800-348-9158, option 3

Website: <https://www.dshs.texas.gov/immunizations/what-we-do/programs>