

Transcript for Registry Consent and Electronic Affirmation

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The broadcast is now starting. All attendees are in listen-only mode.

Patterson: Closed captioning for this presentation is available at <https://tcc.1capapp.com/event/dshs/>. A link will also be provided in the chat. Today, we will be discussing Registry Consent and Electronic Affirmation for the Texas Immunization Registry.

Hello, everyone. My name is Jonathan Patterson. I will be your main presenter today. I am an Interface Analyst with the Texas Immunization Registry. I am joined today by Angela DeLaCruz, who is 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 has completed.

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.

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

- BiDX will be short for Bidirectional data exchange,
- FTP 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.

Let's begin with an overview of registry consent.

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 applicable privacy laws.

Let's briefly cover the laws that create the requirements for immunization registry consent in Texas. Texas House Bill 2641 requires all Health and Human Services information systems that are implemented after September 1st, 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 requirements created by the Texas Administrative Code. 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.

Because of these laws, the registry must reject all records for non-consented patients. This 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 person'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 Antivirals and Immunization Medications records (AIMs for short) for five years even if no consent is on file.

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

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 system.

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 an 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.

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 record, because that risks reaffirming a patient that has withdrawn. Reaffirming a patient that has withdrawn without a new signed consent form is a violation of Texas law.

Now that everyone knows what registry consent is, let's talk about affirmation. This first method of affirmation we'll review today 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 connection.
- 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.

To affirm consent for a patient manually, you will begin by logging into 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.

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

On the next screen, fill out all of the patient's information, and then click the 'Find' button on the right.

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 then 'Submit'.

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 the 'Continue Add' button.

On the next screen, you'll see the Client Summary. If everything looks correct, click 'Continue'.

Finally, you'll select the type of consent the patient signed. The options available on this last page are based on the patient's age. Once you're ready, click Affirm to add the patient to the registry. The patient is now a consented registry client!

You should try to affirm consent soon after receiving the signed consent form (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.

Now let's go over 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 into the ImmTrac2 website to add information manually.

The registry offers two different methods of electronic affirmation:

- Affirmation files, and
- HL7 Affirmation.

Both types of electronic affirmation use the same interface you use to send AIMs. That means FTP sites will send affirmations through their FTP

account and Bidirectional sites will send them through their Webservices connection.

Electronic affirmation is strongly encouraged for your organization to participate in Bidirectional Data Exchange. Your organization should choose and be ready to use one of these methods if you plan to use Bidirectional Data Exchange. 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 your patients' records.

The first method of electronic affirmation we'll cover are the 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 patient's 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.

The specifications for creating affirmation files are covered in the Electronic Standards for Affirmation of Registry Consent, which is available on our forms page. 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.

The second and newest option we'll cover for affirmation 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. 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 yet capable of sending this type of consent.

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 is 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 that'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 the registry consent was signed.

The unique codes 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.

With all the different types of consent and ways to send affirmation electronically, it can sometimes feel a little 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 a 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's record for consent before determining whether to retain or reject recorders.
- 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 one of your patients.

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.

Finally, here are some of the resources available to you from the registry. Related resource guides include:

- The *Electronic Data Exchange Resource Guide*, stock number 11-15231, which provides detailed steps and information on how to establish an FTP 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.

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 other data quality reports.

This concludes our presentation. Thank you very much for your time. In the next presentation we will be covering the bidirectional data exchange testing.

We'll now begin our Q&A session.

>> We don't have any questions at this moment.

>> Patterson: Okay. We can give everybody a little bit of time. It took a while for the questions to come in last time as well.

>> Herrera: Okay. We changed EHRs. How can we register?

>> Patterson: What was the question, if they changed their EHR?

>> Herrera: Correct.

>> Patterson: You just need to let us know that your EHR changed. We would want to perform some testing if you have a data exchange connection with us, to make sure that everything works correctly. But you don't have to submit a new registration of intent or anything like that.

>> Herrera: Next question. So, if a patient is responsible for -- is the patient responsible for getting a consent form?

>> Patterson: We do ask that you offer the consent form to your patients. That's the primary way that we receive affirmation for patients, is from their providers offering the form to them. If your patient goes on our website and downloads the form, they can send it to us. But the main way for affirmations is through providers offering the form.

>> Herrera: Is there a standard for patient name? I have had issues with patients that had consent on file, but the immunization with HL7 was rejected due to name match.

>> Patterson: Hmm. I don't know if we have any published guidelines for patient names. There are certain special characters that we're not able to accept.

>> Herrera: So, I think the question is driving down deeper based off of when they send the patient demographics. And it rejects because of a duplicate match. That's the only reason I can think of that they would be

seeing that issue. So, it is possible for a person to be rejected because the system finds more than one match and can't systematically make that determination that you're sending the right John Smith. So, it flags it as a questionable match in one of the response files that you get back through data exchange, which is in the received folder.

It ends in .CNF extension. So, if the patient resulted in a questionable match, then yeah, the data will be rejected and you have to work with the state directly to resolve the questionable match. Okay. The next question is, can you make the race and ethnicity a hard stop, is it now required in the UI?

>> Patterson: That was updated. It recently made a hard field. For data exchange, it's not yet required just because of health level seven messaging standards. It's not required in those standards yet. And EHRs will need time to update that. On the ImmTrac2 website UI, I believe it is now a requirement.

>> Herrera: If a patient has provided a consent or affirmation, do we need to send their affirmation file with all the future messages?

>> Patterson: Can you repeat that question one more time?

>> Herrera: Sure. If a patient is provided a consent or affirmation, do we need to send their affirmation file with all future immunizations?

>> Patterson: Oh, no. So, you would only send that affirmation once. When you first receive that affirmation, or the consent form, that's when you would send the affirmation. After that, you don't have to send it anymore and we ask that you don't, just because there is that risk that if the patient decides to change their mind and withdraws their consent from the registry, if you keep sending that affirmation with every immunization there's a possibility that you will end up re-adding that patient after they've already withdrawn.

>> Herrera: How can we submit records without patient consent? Our EHR requires us to check the button before it will submit the record.

>> Patterson: That is something you would have to take up with your EHR vendor. If they're requiring you to have registry consent before they'll send the records, then their EHR is configured incorrectly and you would want to bring that to their attention. If they have questions, you can always include us in that conversation so that we can provide confirmation that they need to be sending those records for you.

>> Herrera: For everyone's awareness, most EHR vendors do have a configuration that your staff will have to check whether the patient gives consent to share. And that's probably what you're referring to. So as discussed in the webinar, there's a difference between consent to share and

registry consent. The ideal standard is that regardless of the patient's consent to share, the EHR should send all that data to the registry.

>> Patterson: Yeah. Public health registries are exempt from that consent to share requirement, so you should ask them if they can send those as well.

>> Herrera: Next question. If patients' immunizations are exempt, should they sign a withdrawal form?

>> Patterson: If they're exempt?

>> Herrera: One of those situations where the patient is excluding themselves from vaccines, opting out of getting vaccinations.

>> Patterson: There's no need for them to send a withdrawal form. If they're refusing vaccination, then -- the only time they would need to submit a withdrawal form is if they already had an account with us and changed their mind, somebody had created an account and they no longer want to participate, that's when they would send a withdrawal form. If they're refusing the vaccination, then there's no need for a withdrawal.

>> Herrera: This is more of a clarification. Patient names should not include "baby" correct?

>> Patterson: That is correct. I believe right now our system is set up to reject those if it sees the, word "baby" in the name.

>> Herrera: There's a follow-up question to the previous one that stated, to clarify, the patient has an affirmation on file, but the HL7 is still rejecting as consent not on file.

>> Patterson: All right. In that case, there's a good chance that it's not matching up correctly. You can give us an example of the messages and patients that are being rejected. That way we can compare what's in ImmTrac versus what you're sending. The matching is not exact. ImmTrac, when it receives your messages, is calculating the likelihood of that patient already being in the registry. Sometimes that's not perfect. If you are sending messages for somebody who has consent and is getting rejected, you can bring that our attention. We can check that against what's going on in ImmTrac.

>> Herrera: Next one is, How are you determining new immunizations versus historical immunizations? In this case, COVID?

>> Patterson: So, when you're sending your immunizations to the registry, there's actually a field in the message itself that identifies whether or not it's historical. That should be based on your documentation. If you document it as a new immunization, it should be reported that way. We don't make that determination on our side. That's based entirely on how it's

reported to us.

>> Herrera: The next one is, I received an email from DSHS indicating you are not receiving our vaccines. They are being transmitted every four to five days, however.

>> Patterson: Mmm. So, if you're talking about the COVID-19 vaccinations, there could be a few things going on there. So, there are a lot of data exchange issues that could be at play. It could be your messages aren't being accepted because of a formatting problem. With COVID-19 in particular, there are also some additional requirements for them to correctly decrement from your inventory, which would include things like making sure it's being reported by the correct site, making sure that you have your lot numbers being documented correctly. Those things can also prevent your records from updating correctly. But you want to email us and ask us what the situation is, and we can look into it with you.

>> Herrera: If we do not send a value in MSH22, are immunizations going to reject?

>> Patterson: That depends on a few factors. The biggest one is whether or not you're used bidirectional data exchange. If you are using that, where you are able to send records immediately and request histories back, then yes, MSH22 is always going to be required. If you're using FTP, batch files on a daily or weekly basis, MSH22 is only required if you're using HL7. If you're reporting consent that way, then MSH22 does become required. But otherwise, if you're just doing regular FTP data exchange without consent, then it's not required.

>> Herrera: Okay. This next one is kind of a multipart question. The first question is, I got an email from ImmTrac indicating that I'm reporting under the wrong org code, but when I run a report, there's nothing reported for that. What do I do? And I'll follow up with a second question after you answer.

>> Patterson: So, reporting with the wrong org code, but you've run a report. Okay. So, there could be a couple possibilities here. One of the possibilities, when you're running the reports, up until last week, I believe, the reports were not working correctly in ImmTrac2. If you were trying to run a report for COVID, you wouldn't get results. That should be corrected now. If you run those reports again, you should see the records coming through correctly. As far as reporting under the wrong site, when you were contacted we probably should have told you which sites were reported under and which they should have been reported under.

There is a process where you can transfer immunizations. It depends on whether or not you gave the shots there. So, if you moved the shots to another site, you want to make sure you update the system with that. And

we can update -- once you update that transfer, then we can update the records again to make sure that they're being counted correctly. If, however, you're reporting under the wrong site and that's not where they were given, there's a process we have to go through to remove those records and re-report them.

>> Herrera: I think you said it well.

>> Patterson: Okay.

>> Herrera: The next question is related to that same set of questions. Is there an error report that we can print out to show us if we have any reported immunizations rejected?

>> Patterson: Yeah. So, whenever you send records through the data exchange, it is going to depend on whether you're using a real-time bidirectional or FTP. Most providers are using FTP. With the FTP, when your file is processing, we produce two reports for you. Actually, there's three, but two are related to immunization records. The two that you want to look at are either your received folder. You're going to get a response file. That is HL7 formatted. You're not going to be able to read that easily.

But if your system is able to upload those files, that's something you can ask your EHR to upload. The other one is the Data Quality report, which will give you a list of all messages sent and which ones received errors. It will describe the errors to you. So, for example, if anything gets rejected, for example, maybe a patient gets rejected or the immunization gets rejected because the date is missing for the immunization or something like that, that will all be listed in that DQA report.

We have a guide online called the *HL7 Texas Immunization Registry Error Guide* on our forms page. That explains what all the errors mean. You can look through that guide and it will tell you exactly what the issue is. It will usually give you guidelines on how to resolve it. It should tell you who to contact to resolve it, whether it's your EHR or Texas assistance. If you're doing bidirectional data exchange, unfortunately we don't provide reports.

We are sending responses back to your EHR. Every time there's an error, your EHR will be getting that response and you would want to talk to your EHR about how you could get access to view those errors.

>> Herrera: Does the error report show if we're entering the wrong lot number?

>> Patterson: No. Unfortunately, the error report is not able to check your lot numbers. In fact, I don't think it's going to return any kind of error at all for your lot numbers. So that's something that you would want to monitor. You could run Ad Hoc reports. We do have teams at the registry reviewing that. When we notice that large numbers of incorrect lot numbers

are being reported, we are reaching out to sites. But it's really going to depend a lot on your own active monitoring.

>> Herrera: The next question, we have not been receiving our rejection files. How can we get those?

>> Patterson: You have not been receiving your rejection files. I assume you're probably talking about your Data Quality reports, your response files. You would want to email us. If you're still in the testing phase, especially for FTP, a lot of sites are not getting their response files. So, you can contact us. We will have those files for you and make sure you get some sort of response back. If you're in production, that's a very serious issue. You want to make sure you contact us right away to look into that. We'll probably need to open a ticket. And we may need to download reports for you if they are available and just not being delivered correctly.

>> Herrera: Is TX IIS required?

>> Patterson: For any new immunization, it is. If you're reporting historical, then it is not required. But if you're reporting as new, it is required, because that's how we identify where that shot was given at.

>> Herrera: We are a family practice office. If all adult immunizations are sent, won't they be rejected if they haven't already been set up in ImmTrac2 as a client? This is happening with flu shots for adults.

>> Patterson: It is likely if most of your patients are and you're not collecting consent, most of your records will be rejected. You still need to report them, because you never know which may be on file already. But if that's a major issue for you, then you would definitely want to start recording consent. Offer those forms to your patients and start adding them to the registry. That way your patients' records can be added.

>> Herrera: If our EHR does not interface with ImmTrac2, and you have to add the patient manually, is an affirmation needed?

>> Patterson: Yeah, so if you're adding patients manually right now you do still need to get that consent form before you're allowed to create an account for them. But affirmation would just be that process where after you get the consent form, you're adding the patient. That is affirmation.

>> Herrera: To elaborate, you could do affirmation online and not affirmation electronically through the data exchange.

>> Patterson: Yeah.

>> Herrera: How do I add the consent?

>> Patterson: How do you add consent -- that was the focus of this video. There are the three -- two categories of adding consent, either manually online, or electronically. And we have the two different methods of

electronic affirmation. If you still have questions about those, you can always contact us. These videos will be posted online. Usually it's taking us right now about two weeks for the videos to show up online. And you can watch the video then. And we go over all the different ways you can add consent to the registry. That's what the affirmation process is.

>> Herrera: Your EHR reporting COVID administrations and they were also manually updating ImmTrac. What would be the best way to correct that so the system is corrected and not duplicating?

>> Patterson: So, yeah. That's going to depend on the situation. If you were doing both manual and electronic reporting, in most cases, if you were doing the manual process first and then after the fact your system was sending those messages, typically ImmTrac should already recognize those immunizations were in place and flag the electronic messages as duplicates. But if you do notice that you have duplicate records on your patients, then you're going to need to work with your EHR and with us to get those duplicates removed.

Some EHRs may be able to do that without registry involvement. There's a way of doing that in HL7 messages. But we would still want to know that that had happened. And if your EHR isn't able to take care of that, we have ways of removing those duplicates.

>> Herrera: Those are all the questions we have for now.

>> Patterson: Okay. Well, I want to thank you all again for coming today. I hope this was valuable to you. We do have another webinar coming up in I believe two weeks that is covering the FTP testing process. So, if that's something that's interesting to you, then please keep an eye out for the registration emails. I believe they actually went out a couple days ago. And have a good day.

[End of Session, 1:43 p.m. CT]