



Centers for Medicare & Medicaid Services

Internet Quality Improvement & Evaluation System (iQIES)

**Clinical Laboratory Improvement Amendments
(CLIA)**

**Transfusion-Related Fatalities (TRF) Tracking
User Manual**

Version 1.0

October 6, 2026

Table of Contents

1.	Introduction	1
1.1	Getting Started in S&C – Important Information to Know	1
1.2	iQIES Service Center	4
1.3	Roles and Permissions	5
2.	Overview	6
3.	General Notes	6
4.	Search for a TRF Record	7
4.1	Search	7
4.2	Advanced Search	8
5.	Create and Update a TRF Record	9
6.	Add Notes	11
7.	Add Attachments	12
8.	Update a Laboratory Link	15
9.	Create an Intake from a TRF Record	17
10.	Delete a TRF Record	20
11.	Delete an Incorrectly Created Intake	22

List of Figures

Figure 1: Expandable Field	1
Figure 2: Notification Banner	2
Figure 3: Tool Tip Icon.....	3
Figure 4: Help Icon	5
Figure 5: CLIA TRF	7
Figure 6: Search by CBER Number.....	7
Figure 7: Advanced Search.....	8
Figure 8: Create TRF	9
Figure 9: New Transfusion Related Fatality	10
Figure 10: Add Notes	11
Figure 11: Attachments.....	12
Figure 12: Select File	13
Figure 13: File Selected	13
Figure 14: Attachment	14
Figure 15: Edit TRF	15
Figure 16: TRF Basic Information Page	15
Figure 17: Find Facility	16
Figure 18: Select Related Provider	16
Figure 19: Create Intake.....	17
Figure 20: Intake Basic Information	18
Figure 21: Intake ID for Lab	19
Figure 22: Delete TRF	20
Figure 23: Delete TRF Pop-Up Window	20
Figure 24: Successfully Deleted Green Notification Banner	21
Figure 25: Delete Intake.....	22
Figure 26: Intake Successfully Deleted Green Notification Banner.....	23

List of Tables

Table 1: Notification Banner Color Descriptions 2

1. Introduction

This user manual addresses TRF tracking and ensures that healthcare facilities immediately report and investigate any patient or donor death suspected to be caused by a blood transfusion or collection

For information on other modules, review the [Reference & Manuals](#) on QTSO.

1.1 Getting Started in S&C – Important Information to Know

Below is important general information about iQIES.

- Log in to iQIES at <https://iqies.cms.gov/> with Health Care Quality Information Systems (HCQIS) Access Roles and Profile ([HARP](#)) login credentials. Review the [iQIES Onboarding Guide](#) for further information, if necessary.
- All screenshots included in this manual contain only test data. Current screens in iQIES may be different from what is shown in screenshots below.
- Screenshots are dependent on user role and may not be an exact representation.
- Words highlighted in blue are clickable links.
- A red asterisk (*) indicates a required field.
- Blank fields may have a limited number of characters allowed in that field. If so, the character limit is shown on the bottom left. The blank fields may also be expanded. Click the two 45° parallel lines and drag to the right to enlarge the box. See *Figure 1, Expandable Field*.

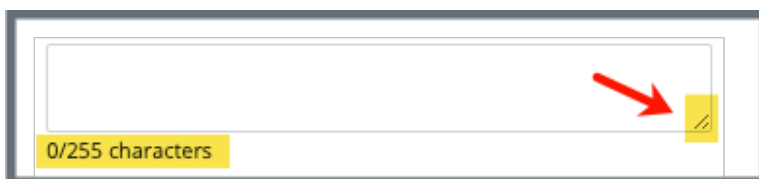


Figure 1: Expandable Field

- iQIES times out after 30 minutes of nonuse and reverts to the login page.
 - iQIES remains up and active as long as it is in use.
 - iQIES gives a five-minute warning before timing out.
 - The session resumes at the last accessed page after reauthentication.
 - Be sure to save data regularly. Pages that require saving are noted in this document, and have a **Save** button on the page.
- iQIES uses a smart search. Once three letters/digits are typed in the search bar, results are shown based on letters/digits entered. The more letters/digits entered, the narrower the search. If any of the results is the correct result, click the result to open.
- Review any notification banners. Some banners may have links to review further information; others may be a reminder of a task that must be completed. See *Figure 2, Notification Banner* and *Table 1, Notification Banner Color Descriptions*. These banners can be closed at any time.

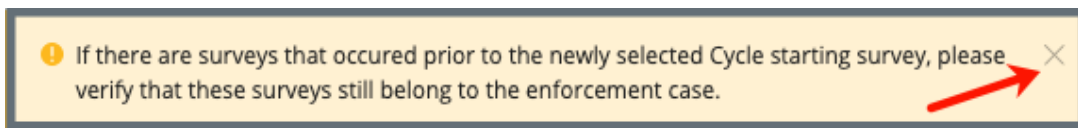


Figure 2: Notification Banner

Table 1: Notification Banner Color Descriptions

Notification Banner Color	Reason
Green	Action was successful
Blue	Informational only
Yellow	Warning. Review for information.
Red	Stop and review. The banner explains the actions that must be taken.

- Review any Tool Tips for additional information to perform an action. Hover over the **i** icon to see the tip. Tool Tips provide additional information in iQIES. Look for the information icon. See *Figure 3, Tool Tip Icon*.

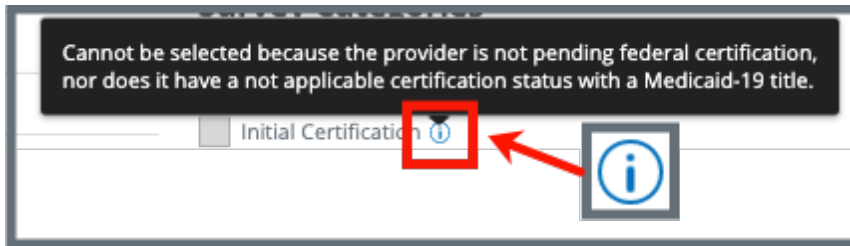


Figure 3: Tool Tip Icon

- Below are the supported browsers for access to iQIES. Be sure to keep your browser updated.

[Chrome](#)

[Edge](#)

1.2 iQIES Service Center

The iQIES Service Center supports users working within the various iQIES components: S&C, Patient Assessment, and Reporting.

Assistance Accessing iQIES: Contact the iQIES SO for your organization

Technical Support: Contact the iQIES Service Center:

Phone: 888-477-7876 (select Option 1)

Email: iQIES@cms.hhs.gov

Idea Portal: Feedback for future iQIES software development: [CCSQ Support Central](#). Click **Idea Portals**.

More information on iQIES: Refer to the [QIES Technical Support Office](#) (QTSO) and the [Quality, Safety, & Education Portal](#) (QSEP). Logging in to HARP may be required before accessing some documentation in QTSO and QSEP.

iQIES reference materials include:

- Links to Training Videos for facilities
- Assessment Management User Manual
- Quick Reference Guides
- Onboarding Guide
- Managing User Information
- Other helpful iQIES material

iQIES training materials on QSEP include S&C Foundation Series Videos.

1.3 Roles and Permissions

iQIES roles allow users to access information pertinent to their area of work. The examples in this document pertain to S&C and require a Centers for Medicare & Medicaid Services (CMS) role with the permission to view or edit the information.

Permissions are ultimately governed by HARP access privileges. Contact the Security Official (SO) for your organization or the iQIES Service Center for issues relating to access and permissions. Review the [iQIES User Roles Matrix](#) for detailed information on roles.

For additional help, refer to <https://iqies.cms.gov/iqies/help> or click the help icon in the top right corner of the screen, see *Figure 4, Help Icon*, for further information.



Figure 4: Help Icon

2. Overview

TRF tracking ensures that healthcare facilities immediately report and investigate any patient or donor death suspected to be caused by a blood transfusion or collection.

Notes:

- This process is for the CMS General User role only
- TRF records are received from the FDA, which uses the Center for Biologics Evaluation and Research (CBER)

3. General Notes

CBER Numbers

- Each CBER number must be unique
- Duplicate CBER numbers cannot be created
- Required fields vary based on the selected TRF type
- A CBER number placeholder requires a reason

Intakes

- A laboratory must be linked to a CLIA facility
- Only one intake can be associated with a TRF record at a time
- TRF records with linked intakes cannot be deleted
- Multiple TRF causes may be selected

Other General Notes

- Notes and attachments can be added to a TRF record
- Deleted TRF records are permanently removed from the system

4. Search for a TRF Record

4.1 Search

4.1.1 Select **CLIA TRF** from the **Survey & Certification** top menu. See *Figure 5, CLIA TRF*. The **Transfusion Related Fatalities** page opens.

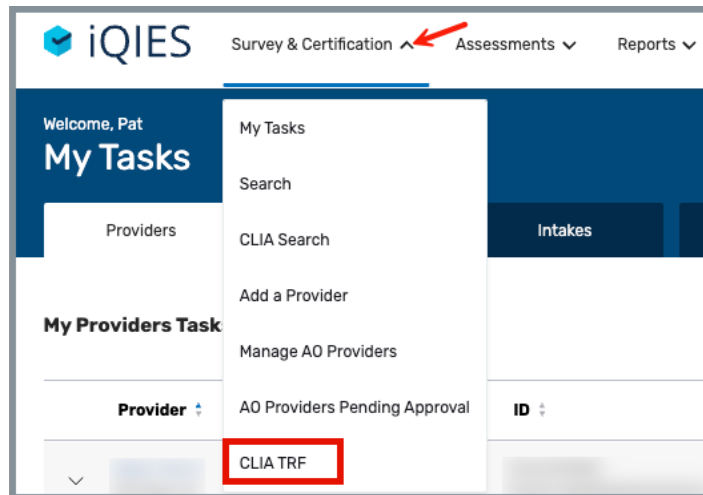


Figure 5: CLIA TRF

4.1.2 Type a CBER number in the search field. See *Figure 6, Search by CBER Number*.

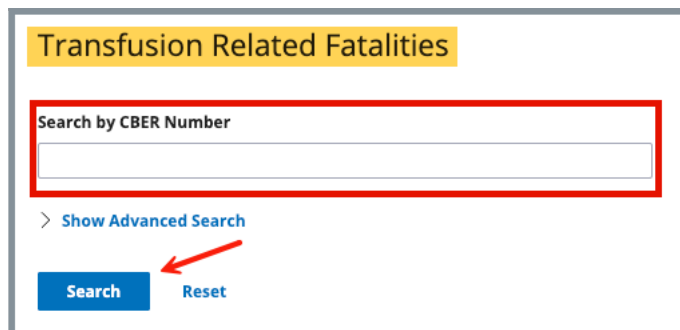


Figure 6: Search by CBER Number

4.1.3 Click **Search**. The associated TRF information is shown.

4.2 Advanced Search

4.2.1 Click the caret next to **Show Advanced Search**. Additional fields open. See *Figure 7, Advanced Search*.

The screenshot shows the 'Transfusion Related Fatalities' search interface. At the top, there's a yellow header bar with the title and a '+ Create TRF' button. Below the header is a search bar labeled 'Search by CBER Number'. A red arrow points to a blue link labeled 'Hide Advanced Search'. Below this, there are three filter sections: 'Status' with a dropdown menu showing 'Select one', 'Pending', and 'Complete'; 'Type' with a dropdown menu showing 'Select one', 'FYI Only', 'Lab - related', 'Hospital - related', 'Both Lab and Hospital', and 'CBER # Placeholder'; and 'Initiated From FDA' with 'From' and 'To' date input fields. A red arrow points to the 'Search' button at the bottom left, and another red arrow points to the 'Reset' link next to it.

Figure 7: Advanced Search

4.2.2 Select by **Status**, **Type**, and **Initiated From FDA**.

Notes:

- Fill out any or all fields.
- Use calendar to select dates for **Initiated From FDA**.
- Filter by **Status**, **Type** or **Initiated from FDA** date range, if desired.

4.2.3 Click **Search**. Matching TRF records appear in the search results table below the search fields.

5. Create and Update a TRF Record

- 5.1 Click **+ Create TRF**. See *Figure 8, Create TRF*. The **New Transfusion Related Fatality** page opens.

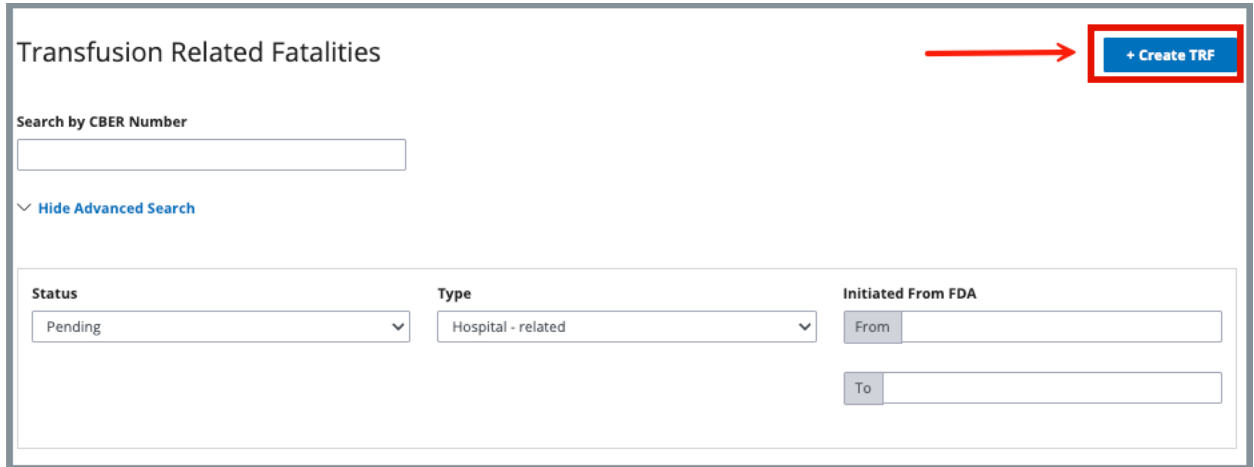


Figure 8: Create TRF

- 5.2 Fill out the information. See *Figure 9, New Transfusion Related Fatality*.

Notes:

- CBER numbers must be unique and must match the number assigned by the FDA.
- A **CBER Gap Reason** must be noted when **CBER # Placeholder** is selected from **Type**.
- Required fields vary based on the selected TRF type.
- New TRF records default to **Pending** status.
- Records created with the **CBER Placeholder** type default to **Complete** status.
- More than one **TRF Cause** can be selected.
- **Other Cause** must be filled out when **Other** is selected under **TRF Cause**. **Other Cause** is a freeform field.
- Click [Find Facility](#) to search for and link a facility. After a facility is linked, the **Find Facility** button changes to **Clear**, which can remove the selected facility and allows selection of a different facility.

New Transfusion Related Fatality

Manage the basic information for this Transfusion Related Fatality (TRF).
All required fields are marked with an asterisk (*)

Transfusion Related Fatality Information

CBER * 	Type * Select one	CBER Gap Reason
Initiated from FDA * mm/dd/yyyy	Status Pending	Type of Follow-up Select one
TRF Cause Select...	Other Cause 	
Facility Name (Type or Search) * 		Find Facility

Additional Dates

Date of Death * mm/dd/yyyy	Notice to RO/ARA mm/dd/yyyy	Report from RO/ARA mm/dd/yyyy
CMS Requested FDA Report mm/dd/yyyy	CMS Receives FDA Report mm/dd/yyyy	FDA Requests Report from CMS mm/dd/yyyy
CMS Final Report to FDA mm/dd/yyyy	Investigation Report Date mm/dd/yyyy	TRF Closure Date mm/dd/yyyy

Figure 9: New Transfusion Related Fatality

5.3 Click **Save**. The **Basic Information** page opens and can be edited.

Note: **Save** is disabled until all required information is completed.

6. Add Notes

- 6.1 Open an existing TRF record.
- 6.2 Click **Notes** on the left menu. The **Add Notes** page opens. See *Figure 10, Add Notes*.

Note: **Add Notes** appears when no notes exist. **Notes** appears when a note already exists. Click **Edit** to add, edit, or update the note.

Figure 10: Add Notes

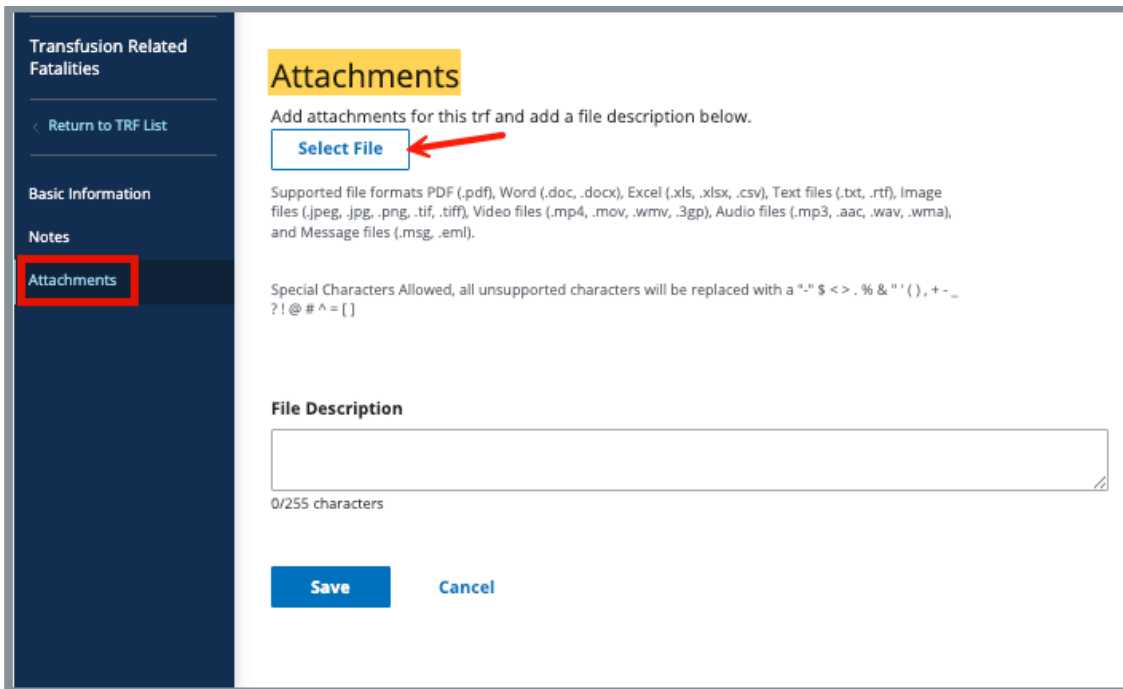
- 6.3 Type notes in the field under **Add Notes**.
- 6.4 Click **Save**. The **Notes** window opens and notes can be viewed and edited.

Note: **Save** is disabled until the note is written or updated.

7. Add Attachments

Note: Only one attachment can be added at a time.

- 7.1 Open an existing TRF record.
- 7.2 Click **Attachments** on the left menu. See *Figure 11, Attachments*. The **Attachments** window opens.



Attachments

Add attachments for this trf and add a file description below.

Select File

Supported file formats PDF (.pdf), Word (.doc, .docx), Excel (.xls, .xlsx, .csv), Text files (.txt, .rtf), Image files (.jpeg, .jpg, .png, .tif, .tiff), Video files (.mp4, .mov, .wmv, .3gp), Audio files (.mp3, .aac, .wav, .wma), and Message files (.msg, .eml).

Special Characters Allowed, all unsupported characters will be replaced with a "- " \$ < > . % & " ' () , + - _
? ! @ # ^ = []

File Description

0/255 characters

Save **Cancel**

Figure 11: Attachments

- 7.3 Click **Select File**. The Windows Explorer pop-up window opens. For Mac users, the Finder pop-up window opens.
- 7.4 Select the file to be attached. See *Figure 12, Select File*.

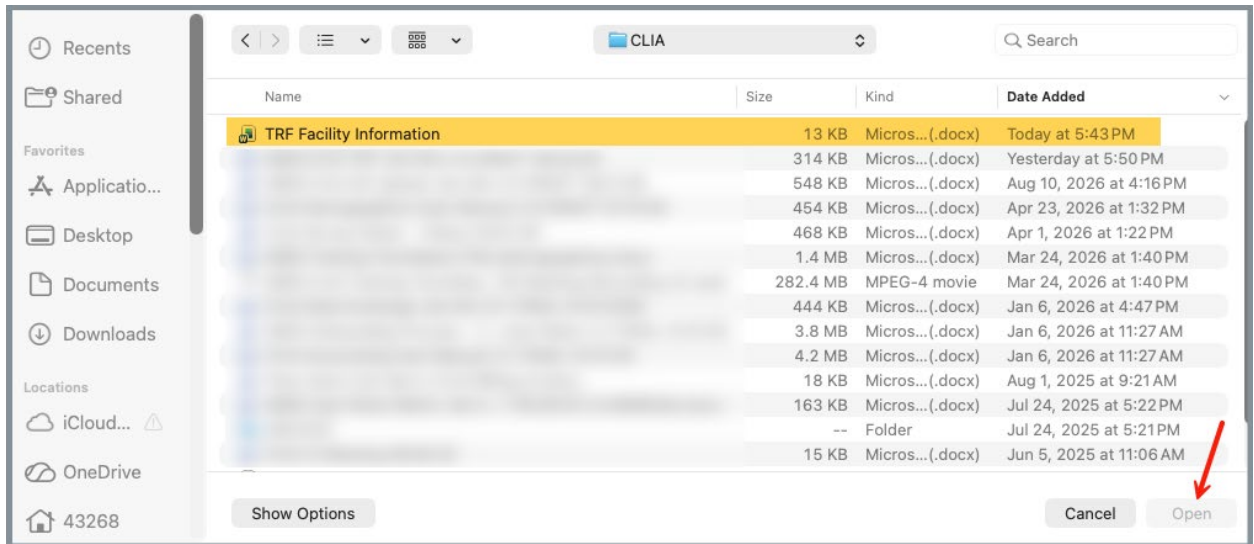


Figure 12: Select File

7.5 Click **Open**.

Note: **Open** is disabled until a file is selected.

7.6 Type a file description in the **File Description** field, if desired. See *Figure 13, File Selected*.

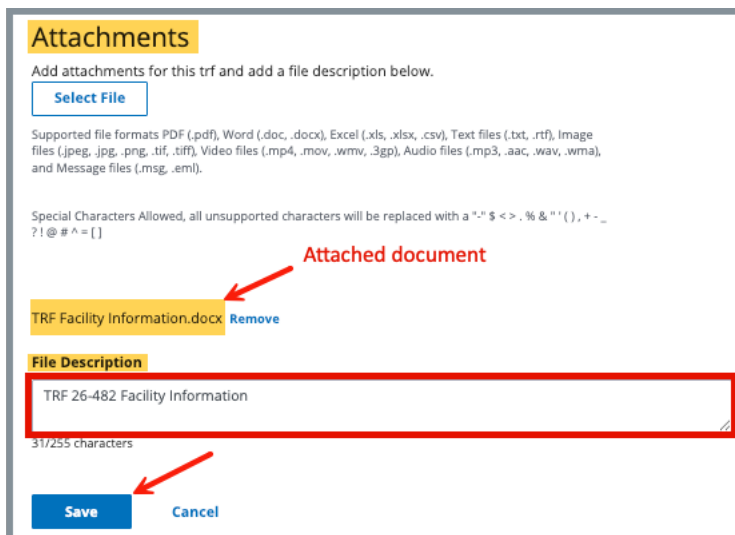


Figure 13: File Selected

7.7 Click **Save**. The **Attachment** page opens. See *Figure 14, Attachment*.

Note: **Save** is disabled until the file is attached.

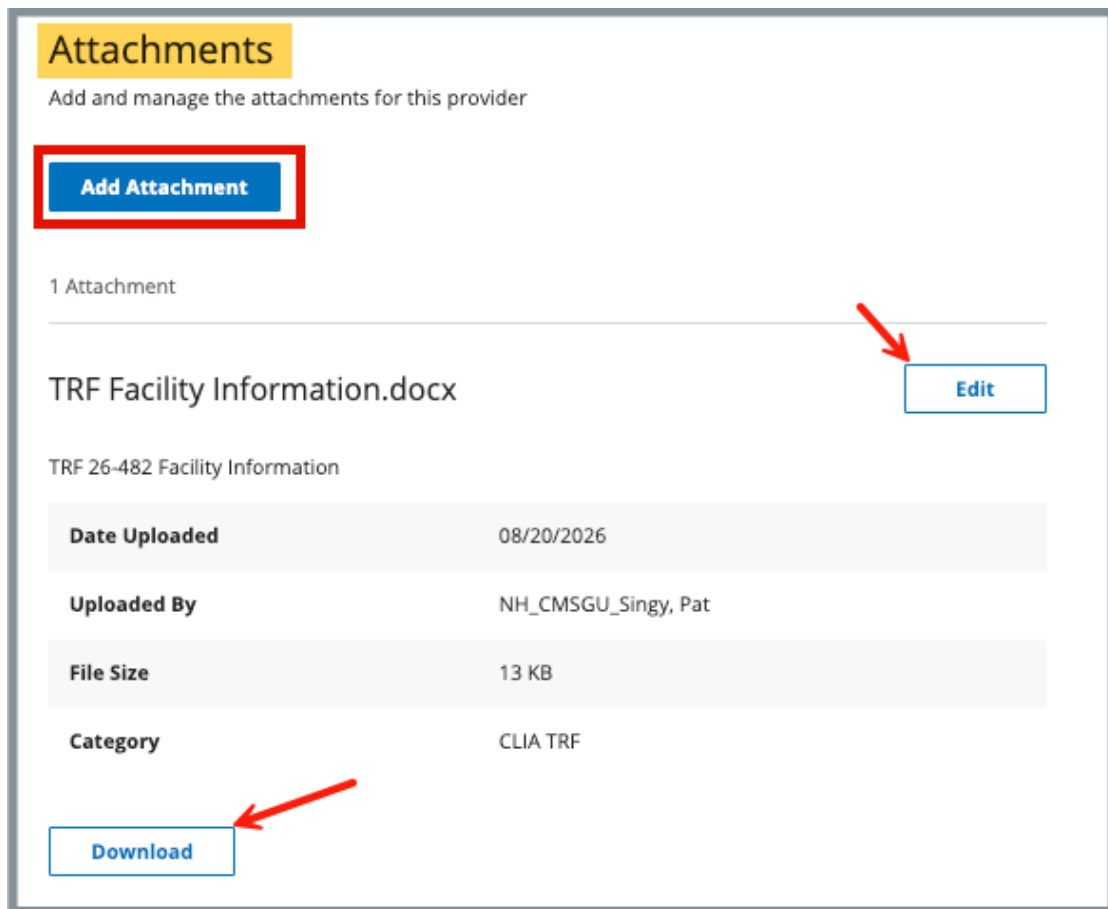


Figure 14: Attachment

- 7.8 Click **Add Attachment** to add additional attachments.
- 7.9 Click **Edit** to update the attachment description or delete the attachment.

Notes:

- The description can be edited.
- The uploaded file itself cannot be edited. It can only be deleted.
- Delete the file and upload a replacement to update it.

- 7.10 Click **Download** to download the attachment.

8. Update a Laboratory Link

8.1 Open an existing TRF record. See *Figure 15, Edit TRF*.

Note: The existing facility is linked.

Basic Information
Manage the basic information for this Transfusion Related Fatality (TRF).

Edit TRF

Transfusion Related Fatality Information

CBER	26-482
Type	Hospital - Related
CBER Gap Reason	No information
Initiated from FDA	2026-08-20
Status	Complete
Type of Follow-up	CMS Requests Investigation
Cause	Other
Other Cause	No information
Facility Name	1-2-3 PEDIATRICS - 1140649 - CLIA

Figure 15: Edit TRF

8.2 Click **Edit TRF**. The editable **Basic Information** page opens. See *Figure 16, TRF Basic Information Page*.

Basic Information
Manage the basic information for this Transfusion Related Fatality (TRF).
All required fields are marked with an asterisk (*)

Transfusion Related Fatality Information

CBER * 26-482	Type * Hospital - related	CBER Gap Reason
Initiated from FDA * 08/20/2026	Status Complete	Type of Follow-up CMS Requests Investigation
TRF Cause Other Select...	Other Cause 	

1-2-3 PEDIATRICS - 1140649 - CLIA

Clear

Figure 16: TRF Basic Information Page

8.3 Click **Clear**.

8.4 Type the facility name or click **Find Facility** to search for a facility. See *Figure 17, Find Facility*. The **Select Related Provider** pop-up window opens. See *Figure 18, Select Related Provider*.

Note: Be sure to select one or more of the following: state, provider or DBA, CCN, State Facility ID, and search criteria.

A screenshot of a web form titled "Find Facility". It features a text input field labeled "Facility Name (Type or Search) *" with a red asterisk. To the right of the input field is a blue button labeled "Find Facility". A red arrow points to the "Find Facility" button.

Figure 17: Find Facility

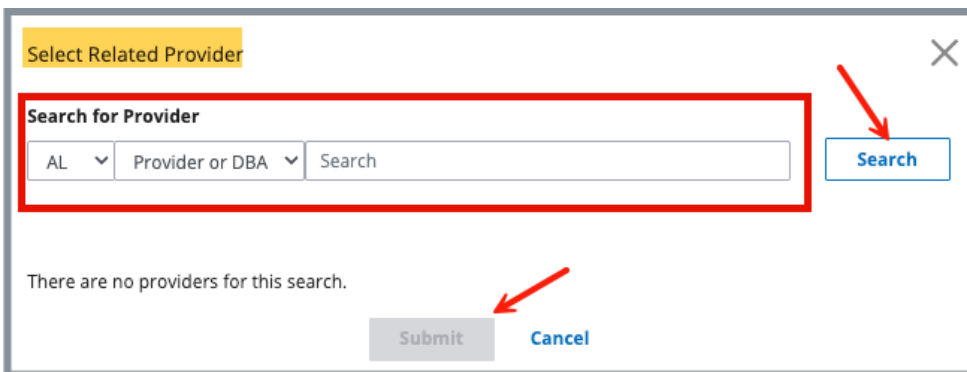
A screenshot of a pop-up window titled "Select Related Provider". The window has a yellow header bar with the title. Below the header is a section titled "Search for Provider" which contains two dropdown menus (one with "AL" selected, the other with "Provider or DBA" selected) and a text input field. To the right of this section is a blue button labeled "Search". A red arrow points to the "Search" button. Below the search section, the text "There are no providers for this search." is displayed. At the bottom of the window are two buttons: a grey "Submit" button and a blue "Cancel" button. A red arrow points to the "Submit" button.

Figure 18: Select Related Provider

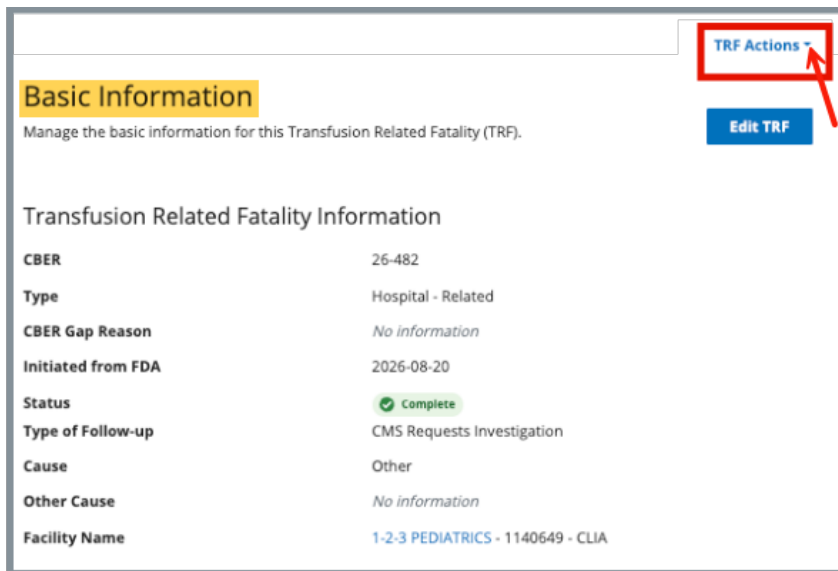
- 8.5 Click **Search**. A list of facilities appears below.
- 8.6 Click the radio button next to the facility to link.
- 8.7 Click **Submit**. The facility is updated.
- 8.8 Click **Save**.

9. Create an Intake from a TRF Record

Notes:

- A CLIA laboratory must be linked to the TRF record to create an intake.
- Review [Manage an Intake User Manual](#) for more details on how to create an intake.

9.1 Open an existing TRF record with a linked laboratory. See *Figure 19, Create Intake*.



Transfusion Related Fatality Information	
CBER	26-482
Type	Hospital - Related
CBER Gap Reason	No information
Initiated from FDA	2026-08-20
Status	Complete
Type of Follow-up	CMS Requests Investigation
Cause	Other
Other Cause	No information
Facility Name	1-2-3 PEDIATRICS - 1140649 - CLIA

Figure 19: Create Intake

9.2 Select **Create Intake** from the **TRF Actions** drop-down menu. The intake **Basic Information** page opens. See *Figure 20, Intake Basic Information*.

Note: The intake **Basic Information** page opens in the same tab.

New Intake
1-2-3 PEDIATRICS
CDL 1401032048
Clinical Laboratory

Basic Information
Enter the basic information for this intake.
All required fields are marked with an asterisk (*)

Intake Type *
☒ Complaint
☐ Incident

Intake Method
Select one

Intake Start Date *
08/21/2026
MM/DD/YYYY

Intake Start Time *
12:39 PM
HH:MM

Tracking ID
Optional ID used by states, additional agencies, or systems.

Sources
Select...

Summary of Complaint
Rich text editor with icons for undo, redo, bold, italic, underline, bulleted list, numbered list, link, unlink, and help.

Intake Subtype *
Select one

Save Section **Cancel**

Figure 20: Intake Basic Information

- 9.3 Fill out the intake information.
- 9.4 Click **Save Section**. The intake **Basic Information** page re-opens and can be edited.
- 9.5 Verify the intake is created on the **TRF Basic Information** page. See *Figure 21, Intake ID for Lab*.

Note: The **Intake ID** is a clickable link.

Basic Information

Manage the basic information for this Transfusion Related Fatality (TRF).

Transfusion Related Fatality Information

CBER	26-482
Type	Hospital - Related
CBER Gap Reason	No information
Initiated from FDA	2026-08-20
Status	✓ Complete
Type of Follow-up	CMS Requests Investigation
Cause	Other
Other Cause	No information
Facility Name	1-2-3 PEDIATRICS - 1140649 - CLIA
Intake ID for Lab	Complaint 2051770

Figure 21: Intake ID for Lab

10. Delete a TRF Record

Notes:

- A TRF record cannot be deleted when a linked intake exists.
- Deleted TRF records are permanently removed from the system.

10.1 Search for an existing TRF. The search result shows under **Search**.

10.2 Click **Delete** under the **Actions** menu. See *Figure 22, Delete TRF*.

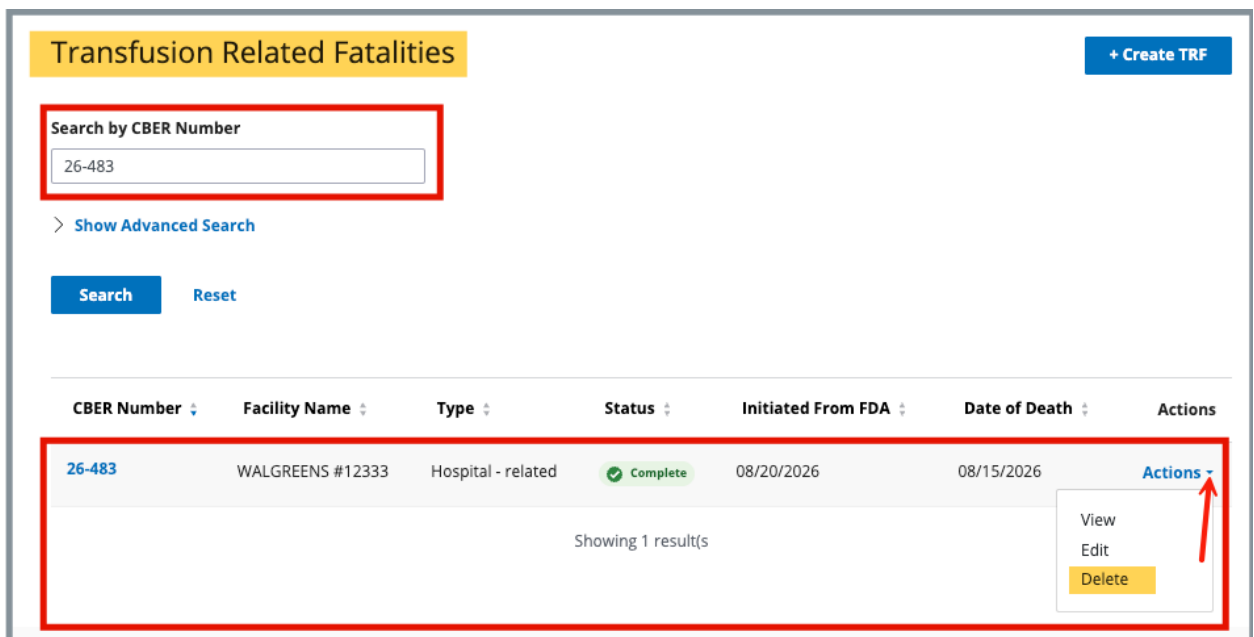


Figure 22: Delete TRF

10.3 The **Delete TRF** pop-up window opens. See *Figure 23, Delete TRF Pop-Up Window*.

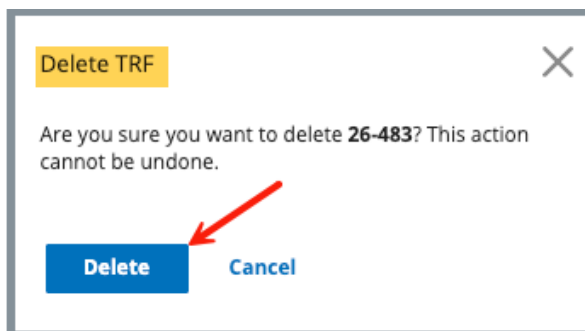


Figure 23: Delete TRF Pop-Up Window

- 10.4 Click **Delete**. The green notification banner opens and states that the TRF was successfully deleted. See *Figure 24, TRF Successfully Deleted Green Notification Banner*.

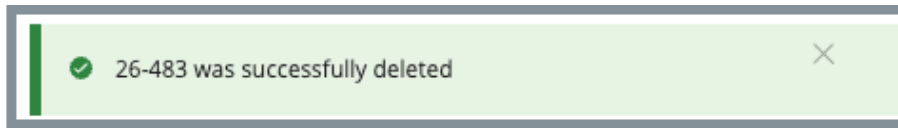


Figure 24: Successfully Deleted Green Notification Banner

11. Delete an Incorrectly Created Intake

Notes:

- Only the CMS General User and the Intake Admin user roles can delete an intake
- Intake must have a status of **Triage/Prioritization** to delete

11.1 Go to the intake.

Note: Open the intake from the TRF record or from the landing page. Go to the Intakes tab and search for the intake ID or facility name.

11.2 Select **Delete** from the **Intake** action drop-down menu. See Figure 25, *Delete Intake*. The **Confirm Intake Deletion** pop-up window opens.

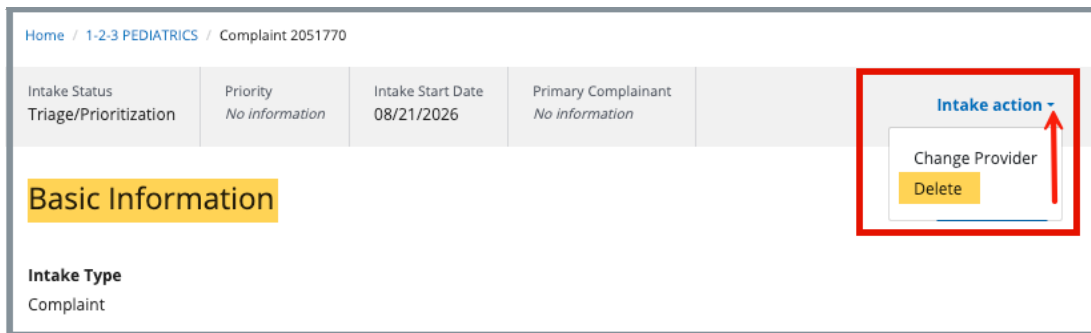
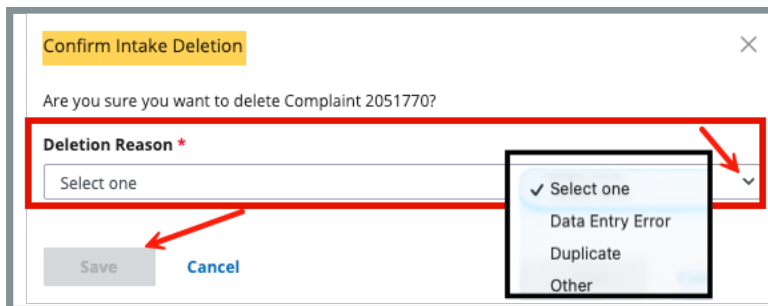


Figure 25: Delete Intake

11.3 Select a deletion reason from the **Deletion Reason** drop-down menu.



11.4 Click **Save**.

Note: **Save** is disabled until a deletion reason is selected.

- 11.5 The green notification banner opens and states that the intake was successfully deleted. See *Figure 26, Intake Successfully Deleted Green Notification Banner*.

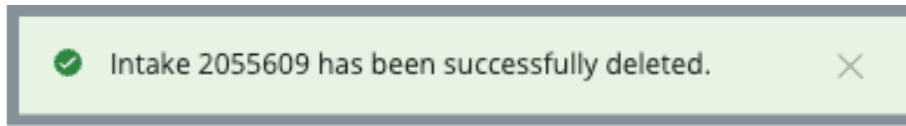


Figure 26: Intake Successfully Deleted Green Notification Banner