

Preventable Adverse Event Reporting
Frequently Asked Questions—FAQs
Last updated 10/2015

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What's **NEW in the Updated FAQ's 08/2015?**

Find a Q&A regarding **IP Behavioral Units** on page 3.

Find information regarding **ICD-10 codes** on page 3-4.

Find information regarding **“Delete PAE Record”** process on page 5.

Find revised answers to **“Report No Events”** on page 8.

Find revised instructions for **Changing PAE contacts** on page 9.

Find new questions/answers on **Foreign Object Retained PAE** on page 14.

Find a Q&A for **Perinatal and Unsafe Blood Administration PAEs** on page 16.

REPORTING REQUIREMENTS

How to begin reporting?

I am new in my position and am responsible for reporting PAEs. What do I need to do in order to report? You need to become familiar with the reporting requirements and reporting system. Start by reviewing the training material found on the Resources page of the website www.PAETexas.org. You will need to revise the designated PAE contacts by completing the [PAE Contact Change Form](#) and submit it to DSHS as directed on the form which is also on the Resources page on the website. DSHS will then send you the TxHSN website URL, your login and temporary password. (Posted 01/2015)

How do I learn more about the Texas Health Care Safety Network (TxHSN)? All upcoming educational presentations or webinars are posted on the PAE website at www.PAETexas.org under Education/Training. Additional prerecorded webinars and PowerPoint presentations are posted on the Resources Page. There will also be an orientation presentation in TxHSN that the designated PAE contacts will be asked to review. (Posted 01/2015)

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Who must report?

Who needs to report? Do Critical access hospitals need to report? Those facilities licensed as a General Hospital or Ambulatory Surgery Center under the Health and Safety Code, Title 4. Health Facilities are required to report health care-associated (HAI) data and designated preventable adverse event (PAE) data as written in the Texas Administrative Code Title 25, Part 1, Chapter 200, Subchapter A, Rule 200.2; Texas Administrative Code Title 25, Part 1, Chapter 133, Subchapter A, Rule 133.49; and Texas Administrative Code Title 25, Part 1, Chapter 135, Subchapter A, Rule 135.26. See Title 25, Part 1, Chapter 200, Subchapter A at [http://texreg.sos.state.tx.us/public/readtac\\$ext.viewtac](http://texreg.sos.state.tx.us/public/readtac$ext.viewtac).

A general hospital is defined as a hospital licensed under the Texas Health and Safety Code Chapter 241 or a hospital that provides surgical or obstetrical services and that is maintained or operated by the state of Texas. This does not include a comprehensive medical rehabilitation hospital. An ASC is defined as a facility licensed under the Texas Health and Safety Code Chapter 243. (Posted 01/2015)

Are rehabilitation hospitals or psych/behavioral hospitals required to report? No, only general hospitals that are NOT medical rehabilitation hospitals are required to report. (Posted 01/2015)

Are Long Term Acute Care facilities (LTACs) required to report PAEs? Yes and no. Some LTACs are licensed as General Hospitals and others are licensed as Special Hospitals under Chapter 241. The ones licensed as General Hospitals (provides surgery, OB services or both) are required to report, while the ones licensed as Special Hospitals (do not provide surgery or OB services) are not required to report. (Posted 01/2015)

Are the Veterans Affairs (VA) or Department of Defense (DOD) hospitals required to report PAEs to the state? No, Veteran Affairs and Department of Defense hospitals are not licensed under the Texas Health and Safety Code and are not maintained or operated

by the State of Texas so are exempt from mandatory state reporting of PAEs. (Posted 01/2015)

Our hospital has an IP Behavioral Unit. It has a different CMS number than the hospital, but has the same geographic address and is included with the hospital's Texas license. Does this unit still have to report PAEs? Yes, all units within a General Hospital that are included in the Texas Facility License must report. (Posted 10/2015)

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What to report?

What needs to be reported for mandatory state reporting? The Preventable Adverse Events (PAEs) and Healthcare Associated Infections (HAIs) are required for mandatory state reporting. These FAQs only review the PAE reporting requirements. Go to www.HAITexas.org to review the HAI reporting requirements. The first phase or tier of PAEs will be reported starting January 1, 2015, and are listed on the PAE website at www.PAETexas.org Reporting page. Also refer to the Current PAE Brochure posted on the Resources page. (Posted 01/2015)

Are the Tier II and Tier III events listed anywhere? Yes. You can see these listed on the Reporting page of the PAE website at www.PAETexas.org and also in the [Current PAE Brochure](#) posted on the Resources page for more information about the PAEs to be reported. (Posted 01/2015)

Why was a phased event list determined? Wouldn't it be easier for hospitals to simply implement all of the required events at one time? It is possible that for some facilities it could be easier. However, in consideration of the preparation, training, and knowledge required for reporting, and with input from the HAI/PAE Advisory Panel, Texas DSHS elected to use a phased-in approach. (Posted 01/2015)

What are the SRE's that have been referenced in your education? SRE is the acronym for Serious Reportable Event. These events have been defined by the National Quality Forum and can be found at http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx and in the following document <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69573>. Texas PAEs are either a SRE or a HAC (see question above). (Posted 01/2015)

Can we get ICD-9 codes for the PAES? We do not have a list of ICD-codes that might be appropriate for all the PAEs. Specific ICD-codes for the actual events are not required; rather there are optional fields for principal discharge diagnosis and surgery/procedure codes. You can find applicable ICD-9 codes for those PAEs that are also Hospital Acquired Conditions (HACs) at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Downloads/FY_2013_Final_HACsCodeList.pdf You can find further information regarding HACs at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond> (Posted 01/2015).

Are ICD-10 codes available for the HACs? You can find information regarding ICD-10 codes for the HACs on the CMS website in Appendix I of the ICD-10-CM/PCS MS-DRG V32 Definitions Manual Table of Contents – Full Titles- Text Version.

By clicking on this link: <https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html> you will see the following in a new browser window:

ICD-10 MS-DRG Conversion Project

This section provides information on the project for using the General Equivalence Mappings (GEMs) to convert the MS-DRGs to ICD-10-CM and ICD-10-PCS. Information is also provided on undertaking similar conversion projects.

The Final ICD-10 MS-DRG v33 logic will be implemented on October 1, 2015 and was subject to rulemaking. For information on the ICD-10 MS-DRG and MCE v33 including ordering the software, see the FY 2016 Acute Inpatient PPS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html> and click on the link for the FY 2016 Final Rule Data Files.

Downloads

[Converting MS-DRGs to ICD-10-CM and ICD-10-PCS - Updated 03/03/15 with new 2015 impact article \[ZIP, 1MB\]](#) 

[Partial Freeze of ICD-9-CM and ICD-10 Codes - Updated 8/5/14 \[PDF, 20KB\]](#) 

[ICD-10 MS-DRG Conversion Project Slides \[PDF, 249KB\]](#) 

[ICD-10-CM/PCS MS-DRG v32 Definitions Manual Table of Contents- Full Titles – Text Version \[ZIP, 3MB\]](#)  

[ICD-10 Medicare Code Editor v32 \(MCE v32 to be used with v32 Definitions Manual\) \[ZIP, 936KB\]](#) 

[ICD-10-CM/PCS MS-DRG v31R Definitions Manual Table of Contents- Full Titles – Text Version \[ZIP, 3MB\]](#) 

[ICD-10 Medicare Code Editor v31R \(MCE v31R to be used with v31R Definitions Manual\) \[ZIP, 835KB\]](#) 

[General Equivalence Mappings FAQs Booklet \(June 2015\) \[PDF, 2MB\]](#) 

[ICD-10 MS-DRGs v32 and v31R Comparison File \[ZIP, 12KB\]](#) 

[2015 Present On Admission \(POA\) Exempt List \[ZIP, 1MB\]](#) 

Click on the link to download “ICD-10-CM/PCS MS-DRG v32 definitions Manual Table of Contents- Full Titles – Text Version” as shown with the blue arrow. Then open the “fulltext” folder and click on “full_appendix_F_J.txt”, and then scroll to Appendix I.

We recommend that you work with the coders at your facility to identify all ICD-10 codes for the CMS Hospital Acquired Conditions. (Posted 10/2015)

When I enter PAE data into TxHSN, it asks for the Record Type. How will we know which Record Type to choose on the Create Record Screen for each of the PAEs? Record type means PAE category. Refer to the [PAE Categories and Tiers](#) document at www.PAETexas.org on the Resources page. (Posted 01/2015)

Vascular Catheter Associated Infection (VCAI) was listed in the original brochure as a reportable PAE. But I do not see it listed anymore. Are we still supposed to report VCAI as a PAE through TxHSN? You are correct that it was listed in the original brochure as a Tier 1 reportable event. However, since Central Line Associated Blood Stream Infection (CLABSI) is reportable to NHSN and to avoid possible duplicate reporting by both HAI and

PAE staff, we will not require a VCAI to be reported as a PAE to TxHSN. The brochure has been updated and can be found on the PAE website on the Resources Page. (Posted 01/2015)

Do observation and inpatient classifications need to be reported? Classification status does not matter. PAE reporting applies to any patient regardless of classification. (Posted 01/2015)

When I enter a PAE, I noticed that there are questions that show in red and have stars next to them. Do these questions have to be answered? Yes, that is correct. The only required question that is not displayed in red and does not have a red star is the question in the Create Record screen that asks for the Record Type (which is the same as the PAE Category). All PAEs require completion of the following questions:

- a) Record Type?
- b) Preventable Adverse Event?
- c) Date Event Occurred (or Discovered if occurrence is unknown)?
- d) Medical Record Number or Patient ID?
- e) Level of harm?
- f) Do you want DSHS to delete this record? (defaults to No)

Completion of remaining questions is optional and encouraged. (Posted 01/2015)

Do I have to fill out the additional root cause questions? No, they are not required. They are optional. (Posted 01/2015)

What was used to formulate the PAE questions in TxHSN? Texas used the Common Formats from the Agency for Healthcare Research and Quality (AHRQ). These can be found at <https://www.psoppc.org/web/patientsafety>. (Posted 01/2015)

If an error displays in red when I save a question package, how do I check the data that it refers to? You can re-enter the question package and find the question that the error refers to. You can correct most errors just by changing the answer and re-saving the question package. Any errors that result from the following information must be corrected in the Edit Persons tab on the Dashboard (Record Summary Screen): Birthdate, Gender, Race, and Ethnicity. You may contact DSHS at PAETexas@dshs.state.tx.us or call 512.776.7676 to request assistance. (Posted 01/2015)

Why would we want DSHS to delete a PAE record? There are several reasons including: The PAE was already entered and is a duplicate, the event does not meet PAE definitions for a reportable event, the PAE is not attributable to your facility, or if the record had been made for training purposes. Other reasons could occur, but if it is in TxHSN in error, then you will want to request it be deleted so it is not included in your facility reports. (Posted 01/2015)

A workflow titled “Delete PAE Record” no longer shows in my workflow box after I have requested to delete a record. Should it display? Up to this point that workflow did appear in your workflow que, but it was actually a workflow for DSHS. Therefore, it no longer appears for the user. If you want to be sure you requested the deletion, you can reenter the General Question Package and view the question and your answer. DSHS will receive the delete request as usual and complete the deletion process. (Posted 10/2015)

Are there any limitations or requirements for the MRN or Pt ID? Any letters, numbers,

spaces or punctuation is acceptable. The system will allow a large number of characters/spaces. (Posted 01/2015)

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How to report?

Is TxHSN the same data portal used for HAI?

TxHSN will be used to enter PAE event data directly. This is the same portal that facilities access to review their HAI reports and make comments. However, HAI data are entered into the National Healthcare Safety Network (NHSN). (Posted 01/2015)

Are there any resources or guidelines for collecting and reporting PAE data? There are resources on the PAE website at www.PAETexas.org. Visit specifically the Resource and Reporting pages. (Posted 01/2015)

Are there any rules as to how to capture the events? Chapter 98 of the Health and Safety Code and Chapter 200 of the Texas Administrative Code do not include any specific rules regarding how PAEs are to be captured. We expect that facilities will determine which events are already being captured and then make that data available to the designated PAE contact if possible. For those PAEs that are not currently being captured, the facility will need to determine the most effective way to ensure that data for these events are reported. (Posted 01/2015)

What is the XML file requirement, example file, test environment? Some facilities may choose to make a XML file that includes the PAE record information, which then can be exported to TxHSN. Contact DSHS at PAETexas@dshs.state.tx.us for more information. The instructions and master template file for the XML export will provide examples. There is no test environment. However, in order to test the system, a facility user can mark an event record for deletion or the xml file may be re-sent to TxHSN with corrections. (Posted 01/2015)

Will Texas Patient Safety Organizations (PSOs) particularly Texas Center for Quality and Patient Safety (TCQPS) automatically upload reporting data to DSHS? We recommend that you discuss this directly with the PSO. Texas DSHS will provide the PAE XML file specifications to the PSO if requested. (Posted 01/2015)

If our facility is participating and reporting to a Patient Safety Organization, do we need to report to the state? Yes, ultimately it is the responsibility of the facility to assure that DSHS required reporting is completed. The PSO can send the data to DSHS electronically on behalf of the facility using XML files through the web services portal. For more information send an email request to PAETexas@dshs.state.tx.us. (Posted 01/2015)

Where can I find more information about Patient Safety Organizations (PSOs)? The following website "PSO Privacy Protection Center" will give you more information: <https://www.psoppc.org/web/patientsafety>.

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When to report?

Is a PAE reported by incident date? Yes, when you create an event record, you must answer “Date Event Occurred (or Discovered if occurrence is unknown)”. (Posted 01/2015)

Do we enter our events monthly? You are strongly encouraged to enter PAEs monthly. Chapter 200.7 states that PAE data shall be submitted within 60 days of the end of the reporting quarter. Refer to the TxHSN PAE Reporting Schedule on the Reporting and Resources pages at www.PAETexas.org. (Posted 01/2015)

Is the PAE requirement per Quarter or Half Year on your calendar? PAE data must be entered within 60 days of the end of the reporting quarter. Reports are available for each facility for each quarter. The half years are listed for the second and fourth quarter because at the conclusion of each half year, the data report is posted on the website for the public to access. Refer to the following table for specific information reporting dates. (Posted 01/2015)

Reporting Quarter	Q1: Jan 1 – Mar 31	H1: Jan 1 – June 30	Q3: Jul 1 – Sept 30	H2: Jul 1 – Dec 31
Facility data submission deadline	Within 60 days of end of reporting quarter			
DSHS takes preliminary data snapshot	Jun 1	Sept 1	Dec 1	Mar 1
DSHS sends email to facilities to review data	~Jun 15	~Sept 15	~Dec 15	~Mar 15
Facility data corrections due	Jun 30	Sept 30*	Dec 31	Mar 31*
DSHS takes final data snapshot	July 1	Oct 1	Jan 1	Apr 1
DSHS sends email to facility to review data summary and make comments	NA	Oct 15	NA	Apr 15
Facility comment period deadline	NA	Oct 30	NA	Apr 30
DSHS review of comments	NA	Nov 15	NA	May 15
Public posting of data summary and approved comments	NA	Dec 1	NA	Jun 1

**Last day to verify no PAEs to report for half year*

If any dates fall on a weekend or holiday submit on

the next business day.

What happens if we have no events to report? Do we have to complete anything? If you have not reported any PAEs for the current half year (6 months e.g., Jan – June, or July - Dec), the workflow “Report No Events” will appear in your Workflow Box on your Main page. You can then click on that workflow and you will be taken to the Workflow Details page. Then click on the Record ID # for your facility. You will then be taken to your facility dashboard. Then click on the question package entitled “Report No Events”. You will see the current year, and the current half year such as “January – June”. Go to the right side of the page and check the “Yes” box under “Facility has nothing to report for this time period.” Then click Save.

DSHS will email facilities quarterly to remind users to log in to TxHSN to review submitted data and, if applicable, to indicate that there were no PAEs to report for the current reporting period. Note that if you check this box and later identify a PAE and enter it into TxHSN for that same time period, TxHSN will automatically uncheck the box (where you previously indicated you did not have any PAEs to report) for you.

Because the Health Care Safety Reports are published on a half year basis, the option to confirm no PAE events is only available on a half year basis. For January – June data, the last day to verify no PAEs to report is September 30. For July – December data, the last day to verify is March 31. If there were no PAEs to report and the facility verifies this, then your facility’s Health Care Safety Report displayed on DSHS website will say “This facility reported zero TxHSN events to the Texas Department of State Health Services for this reporting time period.” If you fail to verify that there were no PAEs to report, then your facility’s report will say “This facility failed to report TxHSN events to the Texas Department of State Health Services for this reporting time period.” (Posted 01/2015, revised 04/2015, **revised 10/2015**)

Are we to report events that we become aware of even if they happened before January 1, 2015? No. Only events that have occurred on January 1, 2015 and thereafter are reportable. (Posted 01/2015)

Do I have to report events that have happened since January 1, 2015 but before we get our login and password? Yes. They are still reportable and can be reported within the designated timeframe per the Reporting Schedule. (Posted 01/2015)

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What will be reported to the public?

What type of data will be available for the public? Reported PAE data will be included in the Consumer and Technical Healthcare Safety Reports that are posted on the DSHS website semiannually on December 1 and June 1. The number of specific PAEs per facility per 6 month time period (January – June and July – December) will be displayed. Also, any approved comments submitted by each facility will be included on these reports. (Posted 01/2015)

Will you be reporting the number of Preventable Adverse Events per PAE category? Yes. (Posted 01/2015)

Do you have an example of the report for the public website? There will be training on accessing the reports in the near future. Here is an example of the PAE section of the Healthcare Safety Report: (Posted 01/2015)

Preventable Adverse Events (PAEs)	
Type of Event	Total Number
Events related to the patient's setting	
Patient death or severe harm associated with the use of restraints or bedrails.	1
Potential criminal activity involving a patient	
Abduction of a patient while at the facility.	1

Will the reporting facility be notified before you release the data? Yes, the designated PAE contacts will first receive an email to review their data and make corrections if needed. Then a second email will be sent with instructions to review data summary and submit comments. The public posting of the data summary and any approved comments will then occur. (Posted 01/2015) [Return to Top](#)

TEXAS HEALTH CARE SAFETY NETWORK (TxHSN)

Who will be required to communicate to the Texas Department of State Health Services (DSHS) if the designated contact terminates his/her employment? Each hospital and ambulatory surgery center will designate up to two designated facility contacts that will be responsible for communications with DSHS. Texas requires that all facilities ensure that communications with DSHS are maintained and monitored even if the position is vacant for any reason (vacation, illness, etc.). The facility person(s) to ensure communications must be determined by the facility. **Request for changes in designated PAE contacts can be made in TxHSN by going into the Facility Record and clicking on the "View/Update PAE Contacts" question package which appears on the facility dashboard. Only a designated contact can do this and only one contact can be changed at a time. Alternatively, you can communicate your request to DSHS by submitting a [PAE Contact Change Form](#) which can be found on the PAE website page Resources under the PAE Took Kit.** (Posted 01/2015, revised 10/2015)

How will I communicate to the Texas Department of State Health Services (DSHS)? Facilities may contact DSHS by email at PAETexas@dshs.state.tx.us or by phone (512.776.7676). (Posted 01/2015)

What types of communications will I receive from DSHS? Designated facility contacts may receive emails, letters, faxes or phone calls from DSHS. (Posted 01/2015)

I can't get into TxHSN. I have never received a username or password. How do I get one? If you are a PAE designated contact for your facility, you will need to contact PAETexas@dshs.state.tx.us to obtain your login details. If you are not currently a PAE designated contact, **a current designated contact can enter you as a new contact. Alternatively a completed [PAE Contact Change Form](#) can be submitted via fax to 512.776.7616 or email to PAETexas@dshs.state.tx.us.** Once DSHS receives your contact information, the contacts will get emails with their TxHSN username and first time password. (Posted 01/2015, revised 10/2015)

I forgot my username and/or password for TxHSN. What do I do now?

If you forgot your username, click on “Reset your password” on the login in page. Now click on “Forgot Username” and enter your email address. You will receive an email from the system with your login username. (Posted 01/2015)

If you forgot your password: a) If you previously completed your security question, click on “Reset your password” on the login page. Enter Username and email address and submit. You will receive an email with a link to the change password page where you will be able to create a new password, or b) you will need to send an email to PAETexas@dshs.state.tx.us requesting a new password. (Posted 01/2015)

What do we do when the designated PAE contact for our facility changes or no longer works for us? Request for changes in designated PAE contacts can be made in TxHSN by going into the Facility Record and clicking on the “View/Update PAE Contacts” question package which appears on the facility dashboard. Only a designated contact can do this and only one contact can be changed at a time. Alternatively, you can communicate your request to DSHS by submitting a [PAE Contact Change Form](#) which can be found on the PAE website page Resources under the PAE Took Kit. (Posted 01/2015, revised 10/2015)

Is it ok to have a different person reporting through NHSN for HAI's and then somebody else reporting the PAEs through TXHSN? Yes. Each facility can have up to two HAI and two PAE designated contacts for reporting. This could be a total of 4 different persons. In some facilities the designated HAI contact(s) may also be a designated PAE contact(s). If the same person(s) is reporting both HAI and PAE, they will only have one login. (Posted 01/2015)

I am not a clinical provider but I am the designated contact to enter PAE data into TxHSN. Will I have to get a special access or certification? The designated PAE contacts whose name(s) have been submitted to DSHS will gain access to TxHSN via log-in and password that has been emailed specifically to each contact. Each facility will decide who will do the reporting. There is not a requirement that it be a clinical provider. (Posted 01/2015)

Do I need a separate log in for each of our facilities? We have a large acute care facility, 2 Critical Access Hospitals and 1 Ambulatory Surgery Center. Maybe. If all of these facilities are on different campuses (different physical addresses) then they will need to report PAE data separately and have a different TxHSN login for each location. If you are still unsure whether your campuses need to report separately or not, you may email PAETexas@dshs.state.tx.us and we will assist you with your inquiry. (Posted 01/2015)

I want to ensure that I am one of the designated contacts since I am over regulatory in my facility. How do I find this out? Send a question with your name, email, and your facility name and facility physical location/address to PAETexas@dshs.state.tx.us. (Posted 01/2015)

What if my hospital system has more than one campus/facility under the same Centers for Medicare and Medicaid Services (CMS) number? Facilities will be required to report separately unless they are physically connected and have the same address. If you are still unsure whether your campuses need to report separately or not, you may email PAETexas@dshs.state.tx.us and we will assist you with your inquiry. (Posted 01/2015)

We have outpatient clinics that operate as departments of the hospital under the hospital's license. In some cases they are physically connected but in other cases they are not. Our understanding is that we are required to report any PAEs that occur in these locations since they are operating under the hospital license. Is that correct? If the OP clinic is physically located in / connected to the hospital, PAEs would be reported under the hospital. An OP clinic that is not physically located in / connected to the hospital, of which it is a department, would have a different State of Texas Regulatory identifier even though it functions under the same hospital CMS number. In this case, it will report separately from its hospital. For questions, send the address/name of those OP Clinic departments that are not physically connected to PAETexas@dshs.state.tx.us and we will determine the appropriate reporting status. (Posted 01/2015)

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PAE RULES AND REGULATIONS

I noticed that the Rules for PAE reporting in the Texas Administrative Code are effective on January 18, 2015. Why are events before that date reportable? According to the Texas Administrative Code, Chapter 200.7, Schedule for HAI and PAE Reporting, facilities will report PAEs as outlined effective January 1, 2015. (Posted 01/2015)

Currently patient falls are documented in the Ambulatory Surgical Center Quality Reporting (ASCQR) program-quality measures. If there is a fall, do we have to report again through another system? Patient falls as well as some other PAEs may also be reportable for other programs/projects or regulations. However, the reportable PAEs are defined in Texas Legislation, Chapter 98 of the Healthcare Safety Code. At this time each applicable facility is mandated to report PAEs to the Texas Department of State Health Services, regardless of any additional reporting requirements. (Posted 01/2015)

What types of confidential and legal protections are in place for reporting hospitals? Please refer to the following sections of the Health and Safety Code: 98.109 Confidentiality; Privilege, Section 98.110 Disclosure Among Agencies and 98.111 Civil Action at <http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.98.htm> (Posted 01/2015)

The training PowerPoint PAE-101 states that enforcement for reporting will be required as part of your licensure; what licensure does that refer too? This referred to the Texas Health and Safety Code Title 4, Health Facilities, Subtitle B Licensing of Health Facilities, Chapter 241 Hospitals and Chapter 243 Ambulatory Surgical Centers. (Posted 01/2015)

If a hospital doesn't comply with the reporting, what will be the consequence? Health and Safety Code; Title 2 Health; Subtitle D Prevention, Control, and Reports of Diseases; Chapter 98 Reporting of Health Care-Associated Infections and Preventable Adverse Events; Subchapter D Enforcement states that noncompliance is subject to the enforcement provisions of the 1) Health and Safety Code Title 4, Health Facilities, Subtitle B Licensing of Health Facilities, Chapter 241 Hospitals, Subchapter C Enforcement and Health and 2) Safety Code Title 4, Health Facilities, Subtitle B Licensing of Health Facilities, Chapter 243 Ambulatory Surgical Centers. These can be found at

<http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.241.htm> and
<http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.243.htm> (Posted 01/2015)

What is the penalty (if any) for non-participation in the state mandated Preventable Adverse Event Reporting program? If a facility fails to comply with state mandatory reporting, the state can suspend or revoke the facilities license or place the facility on probation. (Posted 01/2015)

Will this reporting replace the ambulatory surgical center incident reporting form? No, this reporting does not replace any other previous or current reporting. (Posted 01/2015)

When a hospital reports HAIs or PAEs, does this open that facility for a survey/review by CMS or other regulatory agencies? Currently, site visits are already conducted by the HAI program to verify data integrity of HAI reporting for targeted facilities. A similar process will be implemented as part of the PAE reporting program. If during the data review or while onsite an observed safety issue poses a high level of risk to public health, this information will be shared with our regulatory partners for analysis purposes. It will be up to their discretion if a survey/review of the facility is warranted. Regarding CMS, the PAE data reported to Texas will be available on the public website and can be accessed by anyone from the public. But again, a survey or review from CMS would be at that agency's discretion. More details will follow on PAE auditing processes. (Posted 01/2015)

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NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) / HEALTH CARE-ASSOCIATED INFECTIONS (HAIs)

Where can I find more information about reporting of health care-associated infections and NHSN? Go to the HAI website www.HAITexas.org and send questions to HAITexas@dshs.state.tx.us (Posted 01/2015)

Our facility is not required to report HAI's because we don't perform any of the procedures on that list. So, the only thing we report through NHSN is flu vaccine compliance. Are NHSN and TxHSN related in any way or are they separate? These are two separate web-based systems. Facilities enter HAI surveillance data into NHSN and then Texas uses selected data from NHSN to generate facility-specific reports. PAEs are entered directly into TxHSN. Public reports are generated in the TxHSN software program and will include 1) HAI information that has been imported from NHSN, and 2) PAE information that has been entered into TxHSN by each facility. (Posted 01/2015)

My ASC reports SSI data to NHSN. Should I change my conferring rights for PAE reporting? Refer to the [PAE Reporting Alert for ASCs 091214](#) that is posted under resources on the PAE website. If your facility has already conferred rights to Texas DSHS for HAI, you do not need to confer rights for PAE reporting. (Posted 01/2015)

My facility is a new endoscopy center. We do not do any procedures that require us to report to CMS or NHSN. Do I need to sign up for NHSN? Will that register me for PAE reporting? Check to see if you are required to report Influenza

Vaccination for CMS reporting. If so, you may need to sign up in NHSN for your Influenza Vaccination reporting to CMS. Registering for PAE reporting is entirely separate from NHSN and can be done via email to PAETexas@dshs.state.tx.us. For more information, refer to the [PAE Reporting Alert for ASCs 091214](#) that is posted under resources on the PAE website. (Posted 01/2015)

We are a small CAH and we do not do surgeries. I am still unsure as to whether we are required to report to the DSHS at TxHSN? Are critical access hospitals required to report Health Care-Associated Infections (HAIs)? Yes, critical access hospitals fall under general hospital licensing rules in the state of Texas, and are considered general hospitals for mandatory HAI reporting purposes. They will be required to report if they have an ICU, CCU, NICU or perform any of the designated surgical procedures. (Posted 01/2015)

Are Surgical Site infections also pulled from TxHSN? The SSI data that are reported for CMS or for Texas Healthcare Associated Infection (HAI) reporting are reported via the National Healthcare Safety Network (NHSN) by IP staff. For Texas HAI reporting, the applicable data is then exported from NHSN and imported into TxHSN to populate the HAI tables in the Health Care Safety Reports. Surgical Site Infections that are reportable as a Preventable Adverse Event are listed in Tier 3 and will be reported directly into TxHSN. At this time, none of these are reportable to CMS/NHSN and thus these will remain reportable PAEs through TxHSN. More details on how to report these will follow in 2016. (Posted 01/2015)

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DEFINITIONS/GUIDANCE

Is there a data dictionary for PAEs, and if so, where is it located? You can access Texas Reportable Adverse Events Definitions and Guidance Document on the PAE website under Resources. This document shows definitions from the following: (Posted 01/2015)

- National Quality Forum (NQF), *Serious Reportable Events In Healthcare—2011 Update: A Consensus Report, Appendix B Glossary*, Washington, DC: NQF; 2011. Copyright © 2014 National Quality Forum.
http://www.qualityforum.org/Topics/SREs/Serious_Reportable_Events.aspx
- Agency for Healthcare Research and Quality (AHRQ), *AHRQ Common Formats Version 1.2, User's Guide, Appendix 2 Glossary*, Washington, DC: NQF; 2012.
https://www.psoppc.org/c/document_library/get_file?uuid=b8ce4ed7-aabd-49a7-b883-fd8a673ad7a5&groupId=10218

When is the proper time to assess the level of harm? The AHRQ Common Formats Version 1.2 - 2013 | Users Guide states the following: The AHRQ harm scale is used to document the degree of patient harm that results from patient safety incidents of any and all types. It is to be applied *after* attempt(s) are made to improve a patient's condition following occurrence of an incident. The scale is intended to measure the harm that remains after both the incident and any subsequent "rescue" attempts are completed, or "net iatrogenic harm" (net harm caused by the delivery of care). You can access the AHRQ documents at [ARHQ Common Formats, User's Guides, and Glossary](#). (Posted 01/2015)

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Surgical or Invasive Procedure Event

On the post-operative death of an ASA Class 1 patient, what is the timeframe on that death? Is it a death on the OR table, within 24 hours, 72 hours, 30 days, etc.? The Texas PAE “Post-operative death of an ASA Class 1 Patient” includes all ASA Class 1 patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. The time frame includes intraoperative deaths and deaths immediately post-operative which means within 24 hours after surgery or other invasive procedure was completed or after administration of anesthesia (if surgery/procedure not completed). (Posted 01/2015)

If an event, such as foreign object retained, occurred prior to Jan 1, 2015, and the patient is admitted to facility for surgery related to the event, is the event reportable? If the retained object occurred prior to Jan 1, 2015 it is not reportable. Any retained object that occurs after January 1, 2015 will be reportable. If the event actually occurred in another facility, you should notify that facility and they will be responsible to report it. (Posted 01/2015)

Are you following the NQF definition of when an item is considered retained? Yes, refer to the Texas Reportable Adverse Events Definitions and Guidance Document on the PAE website under Resources for definitions and additional information on this PAE. **Texas will, however, follow the Joint Commission guidelines for when surgery is considered to be completed as noted in the next question/answer. See the Texas Note on page 8 of the Definitions and Guidance Document on the PAE website.** (Posted 01/2015, revised 10/2015)

If a foreign object (e.g. sponge) is found to be missing after the surgical wound has been closed, and the incision is reopened for removal prior to the patient leaving the OR, would this be a reportable PAE? Yes. Texas DSHS has now determined that a foreign object is considered to be retained if it is not intended to remain, and is incidentally found to be in any part of the patient’s body after completion of the skin closure. For bedside procedures, an item is considered to be retained if it is not intended to remain, and is incidentally found to be in any part of the patient’s body after the procedure is complete.” This is consistent with Joint Commission Foreign Object Retained Sentinel Event. See http://www.jointcommission.org/assets/1/18/retained_foreign_objects_faqs.pdf. The Texas Reportable Adverse Events Definitions and Guidance Document (on the PAE website under Resources) has been amended to reflect this determination. (Posted 04/2015)

We had a cardiac catheter sheath break off during withdrawal. An immediate cut down was necessary to retrieve the broken piece of sheath. Would this be reportable as a retained foreign object? Because the procedure was not yet completed (insertion of the vascular plug for hemostasis still remained), this would not be reportable as a foreign object retained after surgery for TxHSN PAE reporting. (Posted 10/2015)

Should a foreign object retained be reported if a piece of equipment breaks off and this is not found out until after the surgery? Yes, this meets the definition of an unintended retention of a foreign object that was introduced into the body during surgery and not removed prior to the end of the surgery, (skin closure) and was not intended to remain in the body. (Posted 10/2015)

If an incorrect intraocular lens is implanted and the error is discovered before the patient's surgery ends and then replaced is this reportable? Yes, it would be considered a wrong procedure because the wrong lens was actually implanted and had to be removed. (Posted 04/2015)

What is the definition of “Anesthesia” as it relates to the PAE Post-operative death of an ASA Class 1 patient? The Additional Specifications in the NQF guidance states this PAE “includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.” NQF does not define anesthesia. However, Texas DSHS has determined that deaths associated with the administration of general anesthesia, regional anesthesia, monitored anesthesia care (MAC), deep sedation/analgesia, and moderate sedation/analgesia (“Conscious Sedation”) are reportable under this PAE. (Posted 04/2015)

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Patient Protection Events

I do not see an AHRQ common format for the Discharge or Release to an unauthorized person. Can you please assist with some definition help on this one? There is not a specific Common Format for this one. This PAE applies to the release of patients who are unable to make their own decisions, e.g., children or cognitively impaired adults. Individual facilities may have their own definition of individuals who do not have decision-making capacity. Refer to the Definitions and Guidance Document in the PAE Tool Kit on the Resources page of the PAE website. (Posted 01/2015)

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Care Management Events

If a patient falls and gets a minor bruise is that a PAE reportable event? No. Only falls that result in patient death or severe harm are reportable. Refer to the Definitions and Guidance Document in the PAE Tool Kit on the Resources page of the PAE website. (Posted 01/2015)

Are we required to report all baby deaths? The baby deaths that are required for Texas Preventable Adverse Event Reporting include deaths (or severe harm) associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility. Refer to the Definitions and Guidance Document and the [Perinatal Algorithm](#) posted on the Resources page on the PAE website for further details. (Posted 01/2015)

What pregnancies are considered low-risk? A low-risk pregnancy refers to a woman aged 18-39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome. (Posted 01/2015)

If a low-risk mother, who is not in labor, presents without fetal heart tones, and it is determined that the fetus is not viable prior to labor induction, would this be a reportable event? No, this would not be reportable as the fetus expired prior to the onset of labor and the death was not associated with labor or delivery in a low-risk pregnancy. (Posted 10/2015)

When is the time frame “while being cared for in a healthcare facility”? When does a person become a patient and when are they no longer a patient for reporting events e.g., falls? 1) A person that enters your facility for the purpose of care is considered to be a patient at the point they have been engaged by a member of the healthcare team; e.g., registration for a lab test or assessment by the emergency room triage nurse. 2) A patient is no longer considered to be a patient at the point that they are no longer under the care of the healthcare team; e.g., the nursing assistant has assisted the patient into the car from an inpatient stay or an ambulatory patient who does need assistance leaves the radiology department following an outpatient test. (Posted 04/2015)

When the same event affects more than one person, how do you enter the data? Each person affected by the event equals a separate and distinct PAE and should be entered as such. The only exception is in reporting Perinatal PAEs. According to the Common Format instructions, if a single event affects the mother, and/or fetus or neonate, report one Perinatal event. (TxHSN reporting format captures information for both.) If a single event affects more than one neonate, enter the most severely affected neonate and note injury to other neonate in the narrative. If more than one neonate is affected, create the event for the most severely affected neonate and note the injury to the other neonate(s) in the narrative. (Posted 10/2015)

What conditions might indicate severe harm associated with unsafe administration of blood or blood products? Considerations for severe harm may include the following but is not limited to:

- Transfusion-associated circulatory overload with or without pulmonary edema.
- Acute hemolytic transfusion reaction (AHTR)--ABO incompatibility is the most common cause of AHTR. Hemolysis is intravascular, causing hemoglobinuria with varying degrees of acute renal failure and possibly disseminated intravascular coagulation (DIC). The severity of AHTR depends on the degree of incompatibility, the amount of blood given, the rate of administration, and the integrity of the kidneys, liver, and heart. An acute phase usually develops within 1 hour of initiation of transfusion, but it may occur later during the transfusion or immediately afterward. Onset is usually abrupt. The patient may complain of discomfort and anxiety. Dyspnea, fever, chills, facial flushing, and severe pain may occur, especially in the lumbar area. Shock may develop, causing a rapid, feeble pulse; cold, clammy skin; low BP; and nausea and vomiting. Jaundice may follow acute hemolysis.
- Transfusion-related acute lung injury--Transfusion-related acute lung injury is an infrequent complication. Acute respiratory symptoms develop, and chest x-ray has a characteristic pattern of noncardiogenic pulmonary edema. This complication is the most common cause of transfusion-related death.
- A high level of psychological pain and distress.
- Transfer to a higher level of care due to event.
- Extended length of stay due to event (Posted 10/2015)

