Preventable Adverse Events 2016 Fall Update

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Content

- **Common PAE Types and Causative Factors from JC**
- **2015 and 2016 H1 PAEs Reported to TxHSN**
- **New Guidance for Sexual Assault, Pressure Ulcers**
- **PAE Reporting Requirements and Guidance for 2017**

Washington Post Article of May 3

"Medical errors now third leading cause of death in the United States"

- **Recent study published in the BMJ analyzed 4 large studies dating 2000-2008**
- **Estimated 251,000 deaths/year in US**
- **700 per day or 9.5% of all deaths**
- **3rd leading cause after heart disease and cancer**

Makary, Martin and Daniel, Micheal; Johns Hopkins University School of Medicine

Loretta Macpherson

- December 2014
- ER for anxiety and med concerns post recent brain surgery
- Fosphentoin (Cerebyx) ordered
- Rocuronium IV given (Zemuron/Esmuron)
- Respiratory/cardiac arrest
- Anoxic brain injury
- Death

Joint Commission Types of Sentinel Events

Review of 2015 Events--Voluntarily Reported N=936

- 13.1% Unintended Retention of a Foreign Body
- 12.9% Wrong patient, Site, Procedure
- 10.4% Suicide
- 10.1% Fall
- 8.7% Delay in Treatment
- 8.7% Operative/Post-op Complications
- 36.1% Other

Summary Data of Sentinel Events Reviewed by The Joint Commission
SE Statistics as of: 7/5/2016

Joint Commission
Root Causes of Sentinel Events

999 Human Factors

849 Leadership

744 Communication

545 Assessment

202 Physical Environment

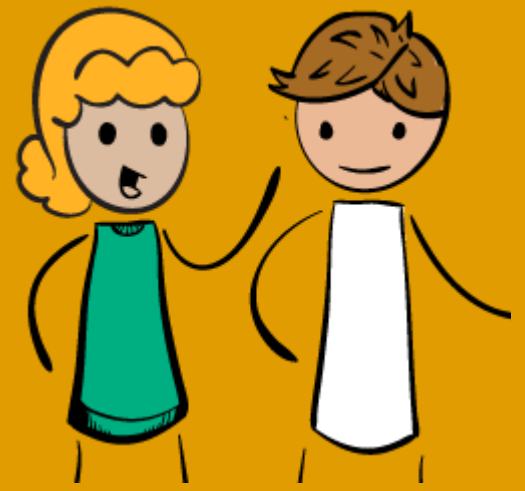
125 Health Information Technology

75 Care Planning

62 Operative Care

60 Medication Use

52 Information Management



Joint Commission
Commonly Reported Causative Factors

Patient Fall

In September 2015, The Joint Commission issued a *Sentinel Event Alert* on Preventing falls and fall-related injuries in health care facilities. Analysis of falls with injury reveals the most common contributing factors pertain to:

- Inadequate assessment
- Communication failures
- Lack of adherence to protocols and safety practices
- Inadequate staff orientation, supervision, staffing levels or skill mix
- Deficiencies in the physical environment
- Lack of leadership

Joint Commission
Commonly Reported Causative Factors

Unintended Retention of Foreign Object

- The absence of policies and procedures
- Failure to comply with existing policies and procedures
- Problems with hierarchy and intimidation
- Failure in communication with physicians
- Failure of staff to communicate relevant patient information
- Inadequate or incomplete education of staff

Joint Commission
Commonly Reported Causative Factors

Wrong-patient, wrong-site, wrong-procedure

Organizations that participated in the Center for Transforming Healthcare's project to develop the Targeted Solution Tool for Safe Surgery identified 29 main causes of wrong site surgeries that occurred during scheduling, in pre-op holding, in the operating room, or which stemmed from the organizational culture as well as potential solutions for these causes.

Scheduling

- Office schedulers do not verify presence and accuracy of booking documents
- Schedulers accept verbal requests for surgical bookings instead of written documents
- Unapproved abbreviations, cross-outs and illegible handwriting

Pre-op holding/holding

- Primary documents – such as consent, history and physical, orders, operating room schedule – are missing, inconsistent or incorrect
- Inconsistent use of site-marking
- Time-out process for regional blocks is inconsistent or absent
- Inadequate patient verification by the team because of rushing or other distractions

Operating room

- When the same provider performs multiple procedures, there is no intraoperative site verification
- Hand-off communication or briefing process is ineffective
- Primary documentation is not used to verify patient, procedure, site, and side immediately prior to incision
- Site marks are removed during prep
- Distractions and rushing occur during time-out, or the time-out occurs before all staff members are ready or before prep and drape
- Time-out is performed without full participation

Organizational culture

- Organizational focus on patient safety is inconsistent
- Staff is passive or not empowered to speak up
- Policy changes are not followed by adequate and consistent staff education

The Joint Commission

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2015 Texas Reported Surgical Event Details

Foreign Objects Retained	Number
Sponge	17
Guidewire or piece of guidewire	11
Lap sponge	5
Towel (resulted in death)	1
Piece of plastic	1
Orthopedic aiming guide	1
ENT micro dilator	1
Ophthalmic trocar	1
Cone tip	1
Part of ureteral stent	1
Part of Cook Cannula	1
Part of drain	1

Wrong Patient
Patient with same last name received cardiac cath—which was needed for her as well
Patient answered to wrong name received colonoscopy instead of esophagram

2015 Texas Reported Surgical Event Details

Wrong Site	Number
Epidural	10
Wrong eye blocked	4
Wrong level spinal decompression	3
Cataract	2
Wrong spinal level	2
Wrong Eye muscle	1
Wrong eye for Macular Deg	1
Wrong side incision (surgery stopped)	1
Wrong shoulder blocked	1
Needle biopsy on wrong kidney	1
Wrong site for nerve block	1
Wrong leg blocked	1
Wrong side hip injection	1
Wrong incision for removal of Spinal stimulator	1
Incision on wrong finger	1
Wrong side for radiofrequency ablation	1
Wrong part of bowel removed	1
Wrong foot heel spur	1
Wrong leg for external fixator	1

Wrong Surgery	Number
Incorrect implant	3
Incorrect IOL for cataract	2
Frenulectomy of tongue rather than upper lip	1
Additional myringotomy with tubes done that was not consented for during ENT surgery	1
Partial fasciotomy done in addition to neuroma decompression (not consented for)	1
Carpal done in addition to trigger finger not consented for	1
Incorrect skull flap	1

2015 PAE Compliance Report

Type of Facility	# Reporting ≥1 PAEs	# of Facilities in TxHSN	% that Reported ≥1 PAE	% of All Facilities in TxHSN That Reported ≥1 PAEs
Hospitals	175	439	40%	19%
ASCs	32	464	7%	4%
All Facilities	**207**	**913**	**N/A**	**23%**

Type of Facility	# That Reported ≥1 PAEs	Total # of Events	Average # of Events	Median	Mode	Range
Hospitals	175	503	2.9			
ASCs	32	42	1.3			
All Facilities	**207**	**545**	**2.6**	**2**	**1**	**1-17**

Texas Preventable Adverse Event Reporting 3 Tier Phase-In Implementation

First Tier PAE Reporting Beginning January 1, 2015

1. Surgeries or invasive procedures involving a surgery on the wrong site, wrong patient, wrong procedure.
2. Foreign object retained after surgery.
3. Post-operative death of an ASA Class 1 Patient.
4. Discharge or release of a patient of any age, who is unable to make decisions, to someone other than an authorized person.
5. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, wrong gas, or are contaminated by toxic substances.
6. Abduction of a patient of any age.
7. Sexual abuse or assault of a patient within or on the grounds of a health care facility.
8. Patient death or severe harm resulting from a physical assault that occurs within or on the grounds of a health care facility.
9. Patient death or severe harm associated with a fall in a health care facility resulting in a fracture, dislocation, intracranial injury, crushing injury, burn or other injury.
10. Patient death or severe harm associated with unsafe administration of blood or blood products.
11. Patient death or severe harm resulting from the irretrievable loss of an irreplaceable biological specimen.
12. Patient death or severe harm resulting from failure to follow up or communicate laboratory, pathology or radiology test results.
13. Patient death or severe harm associated with use of physical restraints or bedrails while being cared for in a health care facility.
14. Perinatal death or severe harm (maternal or neonate) associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility.

Second Tier PAE Reporting Beginning January 1, 2016

1. Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) after total knee replacement or after hip replacement.
2. Iatrogenic Pneumothorax with venous catheterization.
3. Stage III, Stage IV or Unstageable pressure ulcer acquired after admission/presentation to a health care facility.
4. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider.
5. Patient suicide, attempted suicide or self-harm that results in severe harm, while being cared for in a health care facility.
6. Patient death or severe harm associated with patient elopement.
7. Patient death or severe harm associated with an electric shock while being cared for in a health care facility.
8. Patient death or severe harm associated with a burn incurred from any source while being cared for in a health care facility.
9. Patient death or severe harm associated with the introduction of a metallic object into the MRI area.

Third Tier PAE Reporting Beginning January 1, 2017

1. Surgical site infections following a spinal procedure, shoulder procedure, elbow procedure, laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery or cardiac implantable electronic device.
2. Artificial insemination with the wrong donor sperm or wrong egg.
3. Poor glycemic control: hypoglycemic coma.
4. Poor glycemic control: diabetic ketoacidosis.
5. Poor glycemic control: nonketotic hyperosmolar coma.
6. Poor glycemic control: secondary diabetes with ketoacidosis.
7. Poor glycemic control: secondary diabetes with hyperosmolarity.
8. Patient death or severe harm associated with the use of contaminated drugs/devices or biologics provided by the health care facility.
9. Patient death or severe harm associated with the use or function of a device in patient care, in which the device is used or functions other than as intended.
10. Patient death or severe harm associated with intravascular air embolism that occurs while being cared for in a health care facility.
11. Patient death or severe harm associated with a medication error.

Texas PAEs Reported

	2015	2016 H1
Fall with Fracture	202	91
Foreign Object Retained	121	61
Wrong Site Surgery/Invasive Procedure	66	42
Fall with Intracranial Injury	43	29
Wrong Surgery	29	14
Fall with Other Injury	17	12
Perinatal Death or Severe Harm	17	7
Failure to Follow Up	11	10
Sexual Abuse or Assault	8	2
O2 or Other Gas events	8	2
Wrong Patient	7	4
Fall with Dislocation	6	1
Physical Assault	3	0

	2015	2016 H1
Death in ASA Class 1 Patient	2	0
Physical Restraints or Bedrails	2	2
Unsafe Blood or Blood Products	1	0
Irretrievable Loss Irreplaceable Specimen	1	3
Discharge to Unauthorized Person	1	0
Stage 3, 4, Unstageable Pressure Ulcer	--	334
DVT/PE after Knee Surgery	--	39
DVT/PE after Hip Surgery	--	20
Iatrogenic Pneumothorax	--	29
Suicide, Attempted Suicide, Self Harm	--	4
Burn	--	4
Elopement	--	1
Totals	545	711

Pressure Ulcers—SRE and HAC

- HAC codes—include Stage III and IV
- SRE—includes Unstageable
- Unstageable Ulcers are to be reported as a PAE—
  - “Stage III or Stage IV or Unstageable pressure ulcer acquired after admission/presentation to a health care facility.

Pressure Ulcer Reporting Guidance

On Admission and Documented	Progresses to	Reportable?
Skin intact	Stage 3, 4 or Unstageable	Yes
Stage 1	Stage 3	Yes
Stage 1	Stage 4	Yes
Stage 1	Unstageable	Yes
Stage 2	Stage 3	No
Stage 2	Stage 4	Yes
Stage 2	Unstageable	Yes
Stage 3	Stage 4 or Unstageable	No
Stage 4	Unstageable	No

Pressure Ulcer Exclusions

- AHRQ has proposed to remove the Palliative Care exclusion for Pressure Ulcer Reporting (Common Format v2.0)
- Effective Jan 1, 2017 Texas will follow this change.
- A Texas note will be added to the Definitions and Guidance document: “Exclusions for Pressure Ulcer Stage 3, 4, and Unstageable include: Stage 2 progressed to Stage 3, mucosal, arterial, venous and diabetic ulcers.”
- The exclusions for the PSI 03 Pressure Ulcer do not apply for PAE.

Pressure Ulcer Q&A

What if I report Stage 3 ulcer and it progresses to Stage 4?

1. Do not enter another ulcer PAE.
2. Do not request to delete the current PAE.
3. You do not need to edit the current PAE unless you completed documentation in the Specifics QP. If so, edit the Specifics QP.

Deep Tissue Injury Q&A

Are Deep Tissue Injuries that are present on admission and then progress to Stage 3, 4, or Unstageable reportable?

1. Once a DTI progresses to a Stage 3, 4, or Unstageable, it is reportable at that point.
2. If it progresses to Stage 1, 2 or remains the same it is not reportable.
3. Deep Tissue Injuries are not Reportable.

Sexual Abuse/Assault Q&A

Q: If a patient alleges she was raped at the facility, but it is not substantiated by staff, and the police are not going to pursue the case as criminal action, is that reportable?

A. No, if it is not witnessed, not substantiated by clinical evidence, or not admitted to by the perpetrator, it is not reportable as a PAE.

Sexual Abuse/Assault Definitions

- Tier 1 PAE: Sexual abuse or assault of a patient within or on the grounds of a healthcare facility.
- Multiple references used to formulate definitions, including Joint Commission, Texas Penal Codes Title 5, Chapter 21 and 22, and Title 9, Chapter 43.
- A Texas Note will be added to the Definitions and Guidance document defining Sexual Abuse or Assault.
- The guidance will become effective January 1, 2017.

Sexual Abuse/Assault Definitions

- Sexual Abuse or Assault: Nonconsensual sexual contact involving patient and another patient, staff member, or other perpetrator within or on the grounds of the healthcare facility.
- Sexual Contact: Oral, vaginal, or anal penetration or touching/fondling of a patient's sex organ(s) by another individual's hand, sex organ, mouth or object.

Sexual Abuse/Assault Definition

In the case of a child victim, sexual contact is:

- Any touching by a person, including touching through clothing, of the anus, breast, or any part of the genitals of a child; or
- Any touching of any part of the body of a child, including touching through clothing, with the anus, breast, or any part of the genitals of a person.

Sexual Abuse/Assault Definition

In addition, one or more of the following must be present to make the event reportable:

- Any staff-witnessed sexual contact, as described above.
- Admission by the perpetrator that sexual contact, as described above, did occur.
- Sufficient clinical evidence obtained by the facility to support allegations of non-consensual sexual contact.

HACs Reported to TxHSN as PAEs

Events that are only HACs are to be reported if they meet or would meet the HAC ICD-10 Codes--

- ✓ DVT/PE after hip/knee surgery (2016)
- ✓ Iatrogenic Pneumothorax with Venous Catheterization (2016)
- ✓ Poor Glycemic Control (2017)
- ✓ SSIs for certain events (2017)

Third Tier PAE Reporting
January 1, 2017

PRODUCT OR DEVICE EVENTS

1. **Patient death or severe harm associated with the use of contaminated drugs/devices or biologics provided by the health care facility.**

PRODUCT OR DEVICE EVENTS

1. **Patient death or severe harm associated with the use or function of a device in patient care, in which the device is used or functions other than as intended.**

Contaminated Drugs/Devices or Biologics
(Death or Severe Harm)

- Report irregardless of the source of contamination or product
- Contaminants –physical, chemical, biological
- Report events involving medications, biological products, vaccines, nutritional products, expressed human breast milk, medical gases or contrast media.

Contaminated Drugs/Devices or Biologics
(Death or Severe Harm) continued

- Includes:
  - threat of disease that changes patient's risk status for life
  - contaminations both seen and unseen
  - serious infection from contaminated drug/device
  - occurrences r/t improperly cleaned / maintained device.

Use or Function of Device
(Death or Severe Harm)

- Report defects, failures, incorrect use
- Report irregardless if the use is intended or described by the manufacturer.
- Includes implant, medical equipment, medical/surgical supply, HIT device
- Includes, but not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment.

Third Tier PAE Reporting
January 1, 2017

SURGICAL OR INVASIVE PROCEDURE EVENTS

1. **Surgical site infections following spinal, shoulder, elbow procedure; laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery or cardiac implantable electronic device.**

SURGICAL OR INVASIVE PROCEDURE EVENTS

1. **Patient death or severe harm associated with an intravascular air embolism that occurs while being cared for in a health care facility.**

SSIs for PAE Reporting in TxHSN

- A surgical site infection that occurs during the episode of care during which the surgery was performed are reportable as a PAE.
- Reporting of PAE SSIs is completed in TxHSN—NOT in NHSN.
- These infections do not have to meet NHSN criteria.
- The PAE SSIs are Healthcare Acquired Conditions or “HACs”. If an infection occurs that would meet the HAC coding, then it is reportable.

HAC SSIs for PAE Reporting in TxHSN

- See ICD-10 codes for these (surgical procedure code and infection code)
- Certain spinal, shoulder, elbow procedures
- Laparoscopic gastric bypass
- Gastroenterostomy
- Laparoscopic gastric restrictive surgery
- Cardiac Implantable Electronic Device (exception Childrens Hospitals)
- https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html

Section of ICD-10 Codes Orthopedic Surgical HACs*

0RQJXZZ	Repair Right Shoulder Joint, External Approach
0RQK0ZZ	Repair Left Shoulder Joint, Open Approach
0RGJ04Z	Fusion of Right Shoulder Joint with Int Fix, Open Approach
0RGJ07Z	Fusion of Right Shoulder Joint with Autol Sub, Open Approach
0RGJ0JZ	Fusion of Right Shoulder Joint with Synth Sub, Open Approach
0RGJ0KZ	Fusion of R Shoulder Jt with Nonaut Sub, Open Approach
0RGJ0ZZ	Fusion of Right Shoulder Joint, Open Approach
0RGJ34Z	Fusion of Right Shoulder Joint with Int Fix, Perc Approach
0RGJ37Z	Fusion of Right Shoulder Joint with Autol Sub, Perc Approach
AND	
K6811	Postprocedural retroperitoneal abscess
T814XXA	Infection following a procedure, initial encounter
T8460XA	Infect/inflm reaction due to int fix of unsp site, init
T84610A	Infect/inflm reaction due to int fix of right humerus, init
T84611A	Infect/inflm reaction due to int fix of left humerus, init

* Small section of ICD-10 data base for 779 Orthopedic Surgical HACS

Intravascular Air Embolism (Death or Severe Harm)

- ICD-10 code for air embolism following infusion, transfusion and therapeutic injection.
- Excludes death or severe harm associated with certain high risk neurosurgical procedures (head above the heart)
- Includes but not limited to:
  - Head and neck procedures
  - Vaginal and C-section deliveries
  - Spinal instrumentation procedures
  - Liver transplants
  - Low risk procedures e.g. line placement or IVs

Third Tier PAE Reporting
January 1, 2017

CARE MANAGEMENT EVENT

1. **Artificial insemination with the wrong donor sperm or wrong egg.**
2. **Patient death or severe harm associated with a medication error.**

CARE MANAGEMENT EVENT

Poor glycemic control:

1. **Hypoglycemic coma.**
2. **Diabetic ketoacidosis.**
3. **Nonketotic hyperosmolar coma.**
4. **Secondary diabetes with ketoacidosis.**
5. **Secondary diabetes with hyperosmolarity.**

Artificial Insemination

Artificial insemination with the wrong donor sperm or wrong egg.

- Must report the event when you are made aware of it.

Medication Errors (Death or Severe Harm)

- Includes but is not limited to:
  - Over or under dosing
  - Administration of med if known allergy or serious contraindication
  - Drug-drug interaction if no known potential for death or severe harm
  - Failure to administer prescribed drugs
  - Improper use of single or multi-dose vials if leads to dose adjustment problem
  - Wrong administration technic

Medication Errors (Death or Severe Harm)

Excludes:

- reasonable difference in clinical judgment on drug selection/dose
- events associated with allergies that could not have been known or discerned in advance.

Poor Glycemic Control

See ICD-10 codes for these:

- Hypoglycemic coma
- Diabetic ketoacidosis
- Nonketonic hyperosmolar coma
- Secondary diabetes with ketoacidosis
- Secondary diabetes with hyperosmolarity

Poor Glycemic Control

Code	Short Description
HAC 09	MANIFESTATIONS OF POOR GLYCEMIC CONTROL
SECONDARY DIAGNOSES	
E0800	Diab d/t undrl cond w hyprosm w/o nonket hyprgly-hypros coma
E0801	Diabetes due to underlying condition w hyprosm w coma
E0810	Diabetes due to underlying condition w ketoacidosis w/o coma
E0900	Drug/chem diab w hyprosm w/o nonket hyprgly-hypros coma
E0901	Drug/chem diabetes mellitus w hyperosmolarity w coma
E0910	Drug/chem diabetes mellitus w ketoacidosis w/o coma
E1010	Type 1 diabetes mellitus with ketoacidosis without coma
E1100	Type 2 diab w hyprosm w/o nonket hyprgly-hypros coma (NKHHC)
E1101	Type 2 diabetes mellitus with hyperosmolarity with coma
E1300	Oth diab w hyprosm w/o nonket hyprgly-hypros coma (NKHHC)
E1301	Oth diabetes mellitus with hyperosmolarity with coma
E1310	Oth diabetes mellitus with ketoacidosis without coma
E15	Nondiabetic hypoglycemic coma

Poor Glycemic Control Q&A

Q. If a patient has more than one episode of the Poor Glycemic PAE conditions, do I report every episode?

A. Yes, report each episode.

Preventable Adverse Events

Preventable Adverse Events

Home > Infectious Disease Control >Health Care Safety

Preventable Adverse Events (PAE)

Health Care Safety

Revised Definitions and Guidance Document

Sign up for e-mail updates

HCS Home | FAQs | Data | Reporting | Resources | Advisory Panel | Education Training

New FAQs

Preventable Adverse Events, also known as PAEs, can happen in health care. They are not supposed to happen. An example would be surgery on the wrong body part, or a bad injury from a fall. Health care workers try hard to make sure PAEs don't happen.

The State of Texas decided that most hospitals and surgery centers must report PAEs. As of January 1, 2015, PAEs that happen are reported to the State Department of Health.

EMAIL

Ask us your PAE questions!

TxHSN Reporting Schedule

Reporting Quarter	Q1: Jan 1 – Mar 31	H1: Jan 1 – June 30	Q3: July 1 – Sept 30	H2: July 1 – Dec 31
Facility data submission deadline	Within 60 days of end of reporting quarter			
DSHS takes preliminary data snapshot	1-Jun	1-Sept	1-Dec	1-Mar
DSHS sends email to facility users review data	~15-Jun	~15-Sep	~15-Dec	~15-Mar
Facility data corrections due ✶ Last day to verify no PAEs to report for half year	30-Jun	30-Sep✶	31-Dec	31-Mar✶
DSHS takes final data snapshot	1-July	1-Oct	1-Jan	1-Apr
DSHS sends email to facility to review data summary and make comments	NA	15-Oct	NA	15-Apr
Facility comment period deadline	NA	30-Oct	NA	30-Apr
DSHS reviews comments	NA	15-Nov	NA	15-May
Public posting of data summary with approved comments	NA	1-Dec	NA	1-Jun

Request for Deletion of PAE

Additional question added to the General QP when you request deletion:

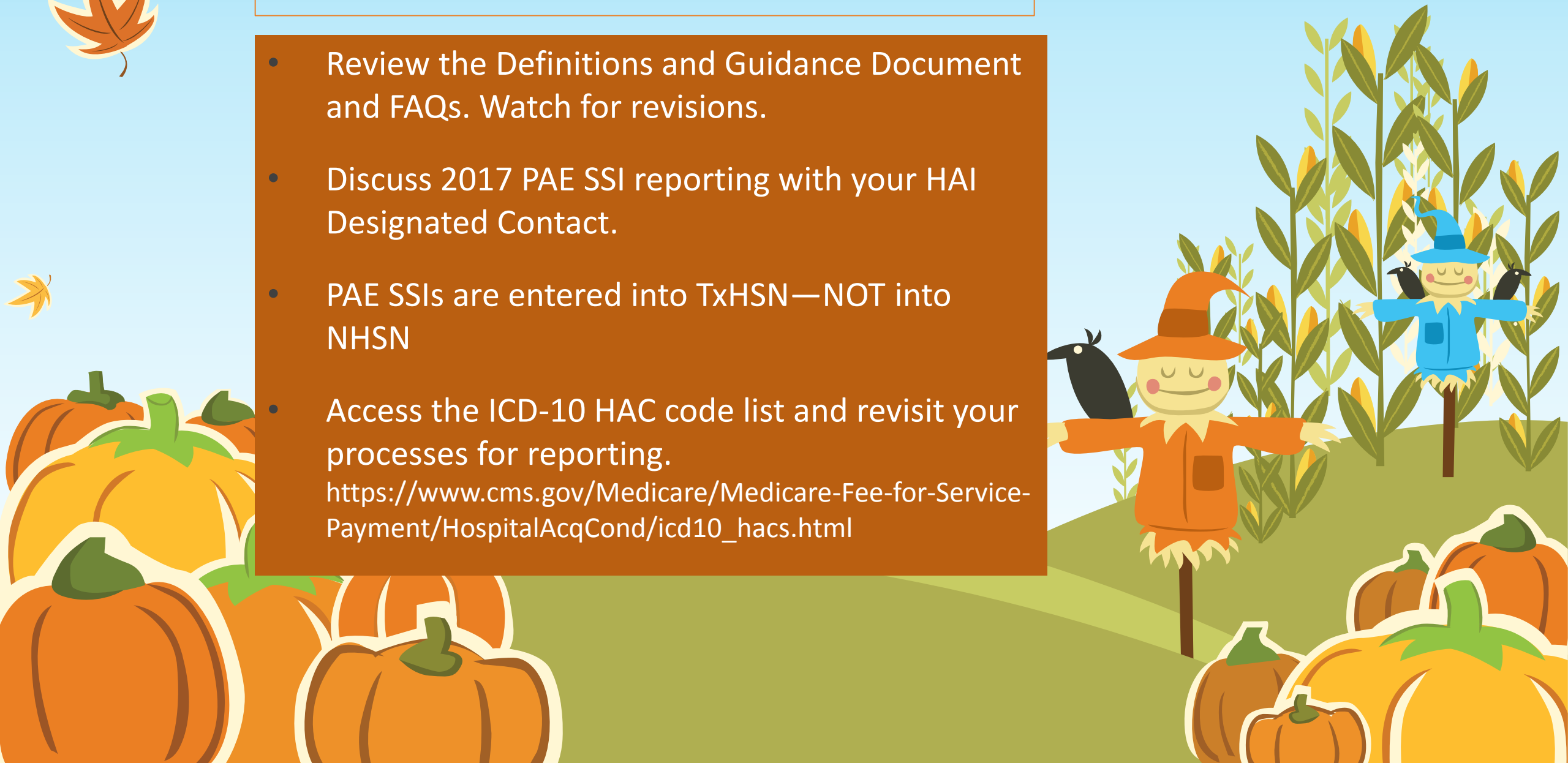
* Do you want DSHS to delete this record?	Yes
Are you sure you want DSHS to delete this record?	Yes
Why do you want DSHS to delete this record?	○ This PAE was already entered (duplicate) ◉ This event does not meet PAE definitions ○ This PAE is not attributed to this facility ○ This was just for training purposes ○ Other
* Please explain why this event does not meet PAE defiinitions.	Example: This injury was assessed at moderate level of harm. Example: This was a Deep Tissue Injury, not a pressure ulcer. Example: This death was in a ASA Class III patient.
Name of person requesting deletion	Vickie Gillespie
Date of deletion request	09/27/2016

* Indicates required field

Save Cancel Help

Take-Aways

- Review the Definitions and Guidance Document and FAQs. Watch for revisions.
- Discuss 2017 PAE SSI reporting with your HAI Designated Contact.
- PAE SSIs are entered into TxHSN—NOT into NHSN
- Access the ICD-10 HAC code list and revisit your processes for reporting.
  https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html



Contact Information

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THE HELP DESK EMAIL is the FIRST and BEST PLACE TO CONTACT FOR QUESTIONS or ASSISTANCE.

Patient Safety in Texas

The purpose of Healthcare Safety reporting is to enhance healthcare transparency in Texas and empower patients to make informed decisions about their healthcare.

Vision: A Healthy Texas

Mission: To Improve Health and Well-being in Texas

Questions?