TxHSN Preventable Adverse Event Reporting Questions Worksheet

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INTRODUCTION

The Preventable Adverse Event Reporting System implemented by Texas Department of State Health Services uses the Agency for Healthcare Research and Quality (AHRQ) Common Formats Hospital Version 1.2 for its reporting structure. The AHRQ Common Formats can be found at https://www.psoppc.org

This document is a listing of the Common Formats questions and can be used for reference or printed to be used as a worksheet.

REQUIRED QUESTIONS

The following data elements (questions) appear in the TxHSN Preventable Adverse Event Reporting Modified AHRQ Format for the First Tier PAEs. ***Note: Gray highlighting indicates a required question***

There are 3 Question Packages for PAE reporting in TXHSN:

A. Create Record Question Package (QP)
B. General Question Package (QP)
C. Specifics Question Package (QP)

All PAEs require completion of the following questions:

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

Completion of remaining questions is optional and encouraged.

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CREATE RECORD QP:

- Record Type
  - ☐ Care Management Event
  - ☐ Environmental Event
  - ☐ Patient Protection Event
  - ☐ Potential Criminal Event
  - ☐ Product or Device Event
  - ☐ Radiologic Event
  - ☐ Surgical or Invasive Procedure Event
- Preventable Adverse Event
  - ☐ Care Management Event
    - Artificial Insemination with the wrong donor sperm or wrong egg
    - Fall – Resulting in burn
    - Fall – Resulting in crushing injury
    - Fall – Resulting in dislocation
    - Fall – Resulting in fracture
    - Fall – Resulting in intracranial injury
    - Fall – Resulting in other injury
    - Patient death or severe harm – associated with a medication error
    - Patient death or severe harm – blood/blood products
    - Patient death or severe harm – failure to follow up or communicate test results
    - Patient death or severe harm – irretrievable loss of irreplaceable biological specimen
    - Perinatal death or severe harm – labor/delivery in low-risk pregnancy
    - Poor Glycemic Control – Diabetic ketoacidosis
    - Poor Glycemic Control – Hypoglycemic coma
    - Poor Glycemic Control – Nonketotic Hyperosmolar coma
    - Poor Glycemic Control – Secondary diabetes with hyperosmolarity
    - Poor Glycemic Control – Secondary diabetes with ketoacidosis
    - Stage 3, 4, or Unstageable Pressure Ulcer
  - ☐ Environmental Events
    - Patient death or severe harm – burn
    - Patient death or severe harm – electric shock
    - Patient death or severe harm – restraints
    - Oxygen or other gas – No gas, wrong gas, or contaminated by toxic substances
  - ☐ Patient Protection Events
    - Patient death or severe harm – patient elopement
    - Patient suicide, attempted suicide, or self-harm resulting in severe harm
    - Discharge/Release patient who is unable to make decisions to non-authorized person.
  - ☐ Potential Criminal Events
    - Sexual abuse/assault on a patient
    - Abduction of a patient/resident of any age
    - Care ordered by someone impersonation healthcare provider
    - Death or severe harm to a patient – physical assault
  - ☐ Product or Device Event
    - Patient death or severe harm – use of contaminated drugs/biologics
    - Patient death or severe harm – unintended function or use of device
    - Patient death or severe harm - use of contaminated devices

- ☐ Radiologic Event
  - Patient death or severe harm – metal in MRI area
- ☐ Surgical or Invasive Procedure Event
  - Air Embolism
  - Death in ASA Class 1 patient
  - DVT/PE – Hip Replacement
  - DVT/PE – Total Knee Replacement
  - Foreign Object Retained After Surgery
  - Iatrogenic Pneumothorax with Venous Catheterization
  - SSI – Bariatric Surgery: Gastroenterostomy
  - SSI – Cardiac Implantable Electronic Device
  - SSI – Elbow procedure
  - SSI – Laparoscopic Gastric Bypass
  - SSI – Laparoscopic Gastric Restrictive Surgery
  - SSI – Shoulder procedure
  - SSI – Spinal procedure
  - Surgery or Invasive Procedure on wrong site
  - Surgery or Invasive Procedure on wrong patient
  - Wrong surgery or wrong invasive procedure performed

- After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)?
  - ☐ Death: Dead at time of assessment.
  - ☐ Severe Harm: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.
  - ☐ Other: Includes moderate harm, mild harm, no harm, and unknown

- Date Event Occurred (or Discovered if occurrence is unknown) __ __ / __ __ / __ __ __ __
  MM DD YYYY
- Medical Record Number or Patient ID_____
- Birthdate __ __ / __ __ / __ __ __ __
  MM DD YYYY
- Gender
  - ☐ Male
  - ☐ Female
  - ☐ Unknown
- Race
  - ☐ American Indian Alaskan Native
  - ☐ Asian
  - ☐ Black or African American
  - ☐ Native Hawaiian or Pacific Islander
  - ☐ White
  - ☐ More than one race
  - ☐ Unknown
- Ethnicity
  - ☐ Hispanic
  - ☐ Not Hispanic or Not Latino
  - ☐ Unknown

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GENERAL QP

- Gender (will autopopulate if entered on Create Record screen; if not can edit in persons tab)
- Birthdate (will autopopulate if entered on Create Record screen; if not can edit in persons tab)
- Age Classification (will autopopulate if birthdate entered on Create Record screen. If not will show as Unknown) (Unknown will not change even when birthdate is entered in persons tab. User should edit this field in the General QP)
  - ☐ Neonate (0-28 days)
  - ☐ Infant (>28 days <1 year)
  - ☐ Child (1-12 years)
  - ☐ Adolescent (13-17 years)
  - ☐ Adult (18-64 years)
  - ☐ Mature adult (65-74 years)
  - ☐ Older adult (75-84 years)
  - ☐ Aged adult (85+ years)
  - ☐ Unknown
- Estimated age (question will appear if Birthdate is not entered on Create Record Screen) enter as numeric value)
- Unit (question will appear if Birthdate is not entered on Create Record Screen)
  - ☐ Days
  - ☐ Months
  - ☐ Years
- Ethnicity (will autopopulate if entered on Create Record screen; if not must edit in persons tab)
- Race (will autopopulate if entered on Create Record screen; if not must edit in persons tab)
- Facility Name (will autopopulate)
- Medical Record Number or Patient ID (will autopopulate)
- Event ID (only required for webservices)
- Date admitted to facility __ __ / __ __ / __ __ __ __ (appears only for hospitals when reporting SSIs)
  MM DD YYYY
- Principal diagnosis at discharge (ICD Code)_____
- Preventable Adverse Event (will autopopulate)
- What type of device issue or HIT issue contributed to the event? (Will trigger a SPECIFICS PACKAGE FOR DEVICES if any of the first three answers are chosen. See SPECIFICS QP—DEVICES that follows)
  - ☐ Device defect or failure, including HIT
  - ☐ Use error
  - ☐ Combination or interaction of device defect or failure and use error
  - ☐ Unknown
  - ☐ Not applicable
- Specify other injury due to fall? _____(this question will appear only when reporting Fall with Other Injury)
- Date Event Occurred (or discovered if occurrence is unknown) (will autopopulate)
- Event Time: __ __ : __ __ AM or PM (if time is 1:00 – 9:00, start with 0, e.g. 03:00 AM)
- Report date __ __ / __ __ / __ __ __ __
  MM DD YYYY
- Anonymous reporter? ☐ (Click box if yes, otherwise skip) (if not anonymous complete remainder of questions regarding reporter)
- Reporter's name _____
- Telephone number (__ __ __) __ __ __-__ __ __ __ (enter numbers, the symbols will auto-appear)
- Email address_____

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- Reporter's job or position
  - ☐ Healthcare professional
    - Type of healthcare professional
      - Doctor, dentist (including student)
      - Nurse, nurse practitioner, physician assistant (including student or trainee)
      - Pharmacist, pharmacy technician (including student)
      - Allied health professional (including paramedic, speech, physical, occupational therapist, dietician)
  - ☐ Healthcare worker (including nursing assistant, patient transport/retrieval personnel, assistant/orderly, clerical/General personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, biomedical engineer, housekeeping, maintenance, patent care assistant, or administrator/manager)
  - ☐ Emergency service personnel (including police officer, fire fighter, or other emergency service officer)
  - ☐ Patient, family member, volunteer, caregiver, or home assistant
  - ☐ Unknown
  - ☐ Other
    - Specify other job or position_____
- What is being reported?
  - ☐ Incident: A patient safety event that reached the patient, whether or not the patient was harmed.
  - ☐ Near miss: A patient safety event that did not reach the patient.
  - ☐ Unsafe condition: Any circumstance that increases the probability of a patient safety event.
- Briefly describe the event that occurred _____
- Where did the event occur?
  - ☐ Inpatient general care area (e.g., medical/surgical unit)
  - ☐ Special care area (e.g., ICU, CCU, NICU)
  - ☐ Labor and delivery
  - ☐ Operating room or procedure area (e.g., cardiac catheter lab, endoscopy area), including PACU or recovery area
  - ☐ Radiology/imaging department, including onsite mobile units
  - ☐ Emergency department
  - ☐ Other area within the facility
  - ☐ Outpatient care area
  - ☐ Outside area (i.e., grounds of this facility)
  - ☐ Unknown
  - ☐ Other
- Was this event associated with a handover/handoff?
  - ☐ Yes
  - ☐ No
  - ☐ Unknown
- Are any contributing factors to the event known?
  - ☐ Yes
    - What factor(s) contributed to the event? (Select all that apply)
      - Environment – Culture of safety, management
      - Environment – Physical surroundings (e.g., lighting, noise)
      - Staff qualifications – Competence (e.g., qualifications, experience)
      - Staff qualifications – Training
      - Supervision/support – Clinical supervision

    - Supervision/support – Managerial supervision
    - Policies and procedures, includes clinical protocols – Presence of policies
    - Policies and procedures, includes clinical protocols – Clarity of policies
    - Data – Availability
    - Data – Accuracy
    - Data – Legibility
    - Communication – Supervisor to staff
    - Communication – Among staff or team members
    - Communication – Staff to patient (or family)
    - Human factors – Fatigue
    - Human factors – Stress
    - Human factors – Inattention
    - Human factors – Cognitive factors
    - Human factors – Health issues
    - Other
        - Specify other contributing factor(s)_____
  - ☐ No
  - ☐ Unknown
- How preventable was the event?
  - ☐ Almost certainly could have been prevented
  - ☐ Likely could have been prevented
  - ☐ Likely could not have been prevented
  - ☐ Almost certainly could not have been prevented
  - ☐ Provider does not make this determination by policy
  - ☐ Unknown

- Procedure date __ __ / __ __ / __ __ __ __ (will appear only in Surgical or Invasive Procedures Category)
  MM DD YYYY

- Was any intervention attempted in order to "rescue" the patient (i.e. to prevent, to minimize, or to reverse harm?
  - ☐ Yes
    - Which of the following interventions (rescue) were documented? (check all that apply)
      - Transfer, including transfer to a higher level care area within facility, transfer to another facility, or hospital admission (from outpatient)
      - Monitoring, including observation, physiological examination, laboratory testing, phlebotomy, and /or imaging studies
      - Medication therapy, including administration of antidote, change in pre-incident dose or route
      - Surgical/procedural intervention
      - Respiratory support (e.g., ventilation, tracheotomy)
      - Blood transfusion
      - Counseling or psychotherapy
      - Unknown
      - Other intervention
        - Specify other_____
  - ☐ No
  - ☐ Unknown

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- After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)? (will autopopulate)
    - ☐ Death: Dead at time of assessment.
    - ☐ Severe Harm: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.
        - What is the anticipated duration of harm to the patient?
            - Permanent: not expected to recover to approximately normal (i.e. patient's baseline)
            - Temporary: expected to recover to approximately normal (i.e. patient's baseline)
            - Unknown
    - ☐ Other: Includes moderate harm, mild harm, no harm, and unknown
- Approximately when after discovery of the incident was harm assessed?
    - ☐ Within 24 hours
    - ☐ After 24 hours but before 3 days
    - ☐ Three days or later
    - ☐ Unknown
- Did, or will, the incident result in an increased length of stay?
    - ☐ Yes
    - ☐ No (or not anticipated)
    - ☐ Unknown
- After the discovery of the incident, was the patient, patient's family, or guardian notified?
    - ☐ Yes
    - ☐ No
    - ☐ Unknown

- Outpatient (appears only for hospitals when reporting SSIs)
    - ☐ Yes
    - ☐ No
- Do you want DSHS to delete this record? (this question defaults to No)
    - ☐ 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
            - No
    - ☐ No

- Name of person requesting deletion (autopopulates with person's name who is logged in)
- Date of deletion request (autopopulates with the date the request to delete is made)

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SPECIFICS QP--SURGICAL OR INVASIVE PROCEDURES CATEGORY (includes Wrong site, Wrong patient, Wrong procedure, Post-operative death of an ASA class 1 patient, Intravascular air embolism, and SSIs)

- Briefly describe the procedure associated with this event_____
- Enter ICD code associated with this event (if available) _____
- What was the patient's documented America Society of Anesthesiologists (ASA) Physical Classifications System class?
  - ☐ Class 1
  - ☐ Class 2
  - ☐ Class 3
  - ☐ Class 4
  - ☐ Class 5
  - ☐ ASA Classification was not documented
- Was the surgery performed as an emergency?
  - ☐ Yes
  - ☐ No
  - ☐ Unknown
- Which combination of anesthesia and sedation was used?
  - ☐ Anesthesia only
    - What type of anesthesia?
      - General anesthesia
        - What was the length of time from induction of anesthesia to the end of anesthesia?
          - ☐ Less than 1 hour
          - ☐ Greater than or equal to 1 hour, but less than 3 hours
          - ☐ Greater than or equal to 3 hours, but less than 5 hours
          - ☐ Greater than or equal to 5 hours
          - ☐ Unknown
      - Regional anesthesia (e.g. epidural, spinal, or peripheral nerve blocks)
      - Local or topical anesthesia
  - ☐ Anesthesia and sedation
    - What type of anesthesia?
      - General anesthesia
        - What was the length of time from induction of anesthesia to the end of anesthesia?
          - ☐ Less than 1 hour
          - ☐ Greater than or equal to 1 hour, but less than 3 hours
          - ☐ Greater than or equal to 3 hours, but less than 5 hours
          - ☐ Greater than or equal to 5 hours
          - ☐ Unknown
        - What was the level of sedation?
          - ☐ Deep sedation or analgesia
          - ☐ Moderate sedation or analgesia (conscious sedation)
          - ☐ Minimal sedation (anxiolysis)
          - ☐ Unknown

- Regional anesthesia (e.g. epidural, spinal, or peripheral nerve blocks)
  - What was the level of sedation?
    - ☐ Deep sedation or analgesia
    - ☐ Moderate sedation or analgesia (conscious sedation)
    - ☐ Minimal sedation (anxiolysis)
    - ☐ Unknown
- Local or topical anesthesia
  - What was the level of sedation?
    - ☐ Deep sedation or analgesia
    - ☐ Moderate sedation or analgesia (conscious sedation)
    - ☐ Minimal sedation (anxiolysis)
    - ☐ Unknown

☐ Sedation only
- What was the level of sedation?
  - Deep sedation or analgesia
  - Moderate sedation or analgesia (conscious sedation)
  - Minimal sedation (anxiolysis)
  - Unknown

☐ None
☐ Unknown

- Who administered (or, if the event occurred prior to administration of anesthesia, person who was schedule to administer) the anesthesia or sedation?
  - ☐ Anesthesiologist
  - ☐ Certified Registered Nurse Anesthetist
    - Was there supervision by an anesthesiologist?
      - Yes
      - No
      - Unknown
  - ☐ Other healthcare professional
    - Who was the other healthcare professional who administered the anesthesia or sedation? _____
- When was the event discovered?
  - ☐ Before anesthesia started or, if no anesthesia used, before procedure started
  - ☐ After anesthesia started, but before incision or start of procedure
  - ☐ After procedure started (incision), but before procedure ended (closure)
  - ☐ At closure, if surgical operation
  - ☐ After procedure ended, but before patient left operation room or other procedure area
  - ☐ During post-anesthesia care / recovery period
  - ☐ After post-anesthesia recovery, but before discharge
  - ☐ After patient was discharged
  - ☐ During anesthesia when no surgical operation or invasive procedure was performed
  - ☐ Unknown
- What was the medical or surgical specialty of the provider of team who performed the procedure?
  - ☐ Anesthesiology
  - ☐ Cardiology
  - ☐ Colorectal surgery
  - ☐ Dentistry, including oral surgery
  - ☐ Dermatology

- ☐ Emergency medicine
- ☐ Gastroenterology
- ☐ Internal medicine
- ☐ Neurological surgery
- ☐ Obstetrics/Gynecology
- ☐ Ophthalmology
- ☐ Orthopedic surgery
- ☐ Otolaryngology
- ☐ Pediatrics
- ☐ Pediatric surgery
- ☐ Plastic surgery
- ☐ Podiatry
- ☐ Pulmonology
- ☐ Radiology, including vascular and interventional
- ☐ Thoracic surgery
- ☐ Urology
- ☐ Vascular surgery
- ☐ Other
  - Specify other specialty_____

- Which best describes the event?

  - ☐ Surgical event
    - Which of the following best characterizes the surgical event?
      - Surgical site infection
        - The SSI was classified as which of the following?
          - ☐ Organ/space
          - ☐ Deep incisional primary (DIP)
          - ☐ Deep incisional secondary (DIS)
          - ☐ Superficial incisional primary (SIP)
          - ☐ Superficial incisional secondary (SIS)
          - ☐ Unknown
      - Bleeding requiring return to the operating room
      - Burn and/or operating room fire
        - Which of the following occurred?
          - ☐ Burn
          - ☐ Operating room fire
          - ☐ Both
      - Incorrect surgical or invasive procedure
        - What was incorrect about the surgical or invasive procedure?
          - ☐ Incorrect patient
          - ☐ Incorrect side
          - ☐ Incorrect site
          - ☐ Incorrect procedure
          - ☐ Incorrect implant by mistake
          - ☐ Incorrect implant because correct implant was not available
          - ☐ Other
            - Specify other incorrect action regarding surgical or invasive procedure_____

- Unintended laceration or puncture
- Dehiscence, flap or wound failure or disruption, or graft failure
- Unintended blockage, obstruction, or ligation
- Unplanned removal of organ
- Other
  - Specify other characterization of event_____

☐ Anesthesia event
- If the event involved anesthesia, which of the following best characterizes the event?
  - Dental injury
  - Ocular injury
  - Peripheral nerve injury
  - Awareness (during anesthesia)
  - Malignant hyperthermia
  - Problem with anesthetic, medical gas, mediation, or other substance administration (Medication or Other Substance QP will follow)
  - Problem with device used in the delivery of anesthesia (Device or Supply, Including Health Information Technology (HIT) will follow)
  - Difficulty managing airway
    - Which of the following best characterizes the airway management problem?
      - ☐ Difficulty during tracheal intubation
      - ☐ Difficulty maintaining airway during procedure
      - ☐ Esophageal intubation
      - ☐ Re-intubation, following extubation, in the operating or recovery room
      - ☐ Other
        - Specify other characterization of airway management problem_____

☐ Major complication that could be associated with either surgery or anesthesia
- Which of the following major complications occurred?
  - Cardiac or circulatory event
  - Central nervous system event
  - Renal failure, impairment, or insufficiency
  - Respiratory failure, requiring unplanned respiratory support, within 24 hours after the procedure
    - Which of the following best describes the respiratory support provided?
      - ☐ Prolonged ventilator support
      - ☐ Re-institution of ventilator following discontinuation
      - ☐ Other
        - Specify other respiratory support_____
  - Other
    - Specify other complication_____

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SPECIFICS QP--FOREIGN OBJECT RETAINED AFTER SURGERY

See SURGICAL OR INVASIVE PROCEDURES QP below followed by:

For FOREIGN OBJECT RETAINED AFTER SURGERY QP, the SURGICAL OR INVASIVE PROCEDURES CATEGORY questions first appear (as shown above) followed by:

- What type of object was retained?
  - ☐ Sponge
  - ☐ Needle (includes needle fragment or microneedle)
  - ☐ Towel
  - ☐ Whole instrument (e.g., clamp)
  - ☐ Instrument fragment
  - ☐ Other
    - Specify other retained object type_____
- Was a count performed for the type of object that was retained?
  - ☐ Yes
    - After counting, what was the reported count status?
      - Incorrect (unreconciled) count
        - Was an x-ray obtained before the end of the procedure to detect the retained object? Highlighted did not appear in model but should have
          - ☐ Yes
          - ☐ No
            - Was the retained object radiopaque (i.e., detectable by x-ray)?
              - Yes
              - No
              - Unknown
          - ☐ Unknown
      - Correct (reconciled) count
  - ☐ No, object "countable"
  - ☐ No, object not "countable"
  - ☐ Unknown

SPECIFICS QP--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

See Medication QP below

SPECIFICS QP--PATIENT DEATH OR SEVERE HARM ASSOCIATED WITH UNSAFE ADMINISTRATION OF BLOOD OR BLOOD PRODUCTS

- What type of blood product was involved?
  - ☐ Whole Blood
  - ☐ Red Blood Cells
  - ☐ Platelets
  - ☐ Plasma
  - ☐ Cryoprecipitate
  - ☐ Granulocytes
  - ☐ Lymphocytes
  - ☐ Albumin
  - ☐ Factors (e.g., VII, VIII, IX, AT III)
  - ☐ IV immunoglobulin
  - ☐ RhIg
  - ☐ Other
    - Specify other blood product_____
- What was the International Society of Blood Transfusion (ISBT) 8 digit product code for the product associated with the event? _____
- Which of the following best characterizes the event? (This question defaults to Incorrect action)
  - ☐ Incorrect action (e.g., patient given blood of wrong ABO type)
    - What incorrect action was involved in administering the blood or blood product?
      - Incorrect patient
      - Incorrect ABO/RH type
      - Incorrect product (e.g., giving heterologous blood product when autologous blood product should have been given)
      - Incorrect sequence of administration of products
      - Incorrect use of expired or unacceptably stored products
        - Was a two-person, three-way check documented? (This question is asked for each of the above choices)
          - ☐ Yes
          - ☐ No
          - ☐ Unknown
      - Incorrect volume (e.g., number of units or milliliters)
        - What was the volume?
          - ☐ Too much/too many
          - ☐ Too little/too few
          - ☐ Unknown
      - Incorrect IV fluid (i.e., administered product with incorrect IV fluid)
      - Incorrect timing (e.g., delay in administration)
      - Incorrect rate
        - What was the rate of administration?
          - ☐ Too fast

- ☐ Too slow
- ☐ Unknown

    - Unknown
    - Other
        - Specify other incorrect action_____

- During which stage was the event discovered (regardless of the stage when it originated)?
    - Product test or request
    - Sample collection
    - Sample handling
    - Sample receipt
    - Sample testing
    - Product storage
    - Available for issue
    - Product selection
    - Product manipulation
    - Request for pickup
    - Product issue
    - Product administration (transfusion or infusion)
    - Post-transfusion or administration
    - Unknown
    - Other
        - Specify other stage when discovered_____
- During which stage did the event originate (regardless of the stage when it was discovered?
    - Product check-in
    - Product test or request
    - Sample collection
    - Sample handling
    - Sample receipt
    - Sample testing
    - Product storage
    - Available for issue
    - Product selection
    - Request for pickup
    - Product issue
    - Product administration (transfusion or infusion)
    - Post-transfusion or administration
    - Unknown
    - Other
        - Specify other stage when originated_____

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SPECIFICS QP--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

- Immediately prior to delivery, what was the best estimate of completed weeks of gestation?
  - ☐ 20-<36 weeks
  - ☐ 36-<38 weeks
  - ☐ 38-<42 weeks
  - ☐ 42 weeks or more
  - ☐ Unknown
- Was the mother a primipara?
  - ☐ Yes
  - ☐ No
  - ☐ Unknown
- How many fetuses were in this pregnancy? (enter a numerical value) _____
-
- Who was affected by this event? (check all that apply)
  - ☐ Mother
    - Which adverse outcome(s) did the mother sustain? (check all that apply)
      - Hemorrhage requiring transfusion
      - Eclampsia
      - Magnesium toxicity
      - Infection
        - Which of the following maternal infections?
          - ☐ Chorioamnionitis
          - ☐ Endometritis
          - ☐ Other
            - Specify other infection_____
      - Injury to body part or organ
          - ☐ Uterine rupture
          - ☐ Third- or fourth-degree perineal laceration
          - ☐ Ureter
          - ☐ Bladder
          - ☐ Bowel
          - ☐ Other
            - Specify other body part or organ_____
      - Death
      - Other
  - ☐ Neonate(s)
    - What was the 5-minute Apgar score? (enter numeric value)_____
    - Which adverse outcome(s) did the neonate sustain? (check all that apply)
      - Birth trauma / injury as listed under ICD-9-CM 767 or ICD-10-CM P10-P15
        - Which birth trauma / injury?
          - ☐ Subdural or cerebral hemorrhage
          - ☐ Injury to brachial plexus, including Erb's or Klumpke's paralysis
          - ☐ Other
            - Specify other birth injury / trauma_____

- Five-minute Apgar < 7 and birthweight > 2500 grams
- Anoxic or hypoxic encephalopathy
- Seizure(s)
- Infection (e.g., group B strep)
- Unexpected death
- Other
  - Specify other adverse outcome for neonate_____

- What was the date of delivery? __ __ / __ __ / __ __ __ __
  MM DD YYYY

- Number of live births (enter numeric value)_____
- What was the neonate's birthweight (or weight of stillborn)? (grams) (enter numeric value)____
- Was labor induced or augmented?
  - ☐ Induced
  - ☐ Augmented
  - ☐ Neither
  - ☐ Unknown
- What was the mode of delivery? (check one)
  - ☐ Vaginal delivery
  - ☐ Attempted vaginal delivery followed by Cesarean section
  - ☐ Cesarean section
  - ☐ Unknown
- Regardless of the final mode of delivery, what instrumentation was used to assist vaginal (or attempted vaginal) delivery?
  - ☐ Vacuum
  - ☐ Forceps
  - ☐ Vacuum followed by forceps
  - ☐ None
  - ☐ Unknown

TxHSN Preventable Adverse Event Reporting Questions Worksheet

SPECIFICS QP--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

- Was the fall unassisted or assisted? (Check one)
  - ☐ Unassisted
  - ☐ Assisted
  - ☐ Unknown
- Was the fall observed?
  - ☐ Yes
    - Who observed the fall? (Check First Applicable)
      - Staff
      - Visitor, family, or another patient, but not staff
  - ☐ No
  - ☐ Unknown
- Prior to the fall, what was the patient doing or trying to do? (Check one)
  - ☐ Ambulating without assistance and without an assistive device or medical equipment
  - ☐ Ambulating with assistance and/or with an assistive device or medical equipment
  - ☐ Changing position (e.g., in bed, chair)
  - ☐ Dressing or undressing
  - ☐ Navigating bedrails
  - ☐ Reaching for an item
  - ☐ Showering or bathing
  - ☐ Toileting
  - ☐ Transferring to or from bed, chair, wheelchair, etc.
  - ☐ Undergoing a diagnostic or therapeutic procedure
  - ☐ Unknown
  - ☐ Other
    - Specify other activity the patient was doing prior to the fall_____
- Prior to the fall, was a fall risk assessment documented?
  - ☐ Yes
    - Was the patient determined to be at increased risk for a fall?
      - Yes
      - No
      - Unknown
  - ☐ No
  - ☐ Unknown
- At the time of the fall, were any of the following risk factors present? (check all that apply)
  - ☐ History of previous fall
  - ☐ Prosthesis or specialty / prescription shoe
  - ☐ Sensory impairment (vision, hearing, balance, etc.)
  - ☐ None
  - ☐ Unknown
  - ☐ Other
    - Specify other risk factors_____
- Which of the following were in place and being used to prevent falls for this patient? (check all that apply)
  - ☐ Assistive device (e.g., wheelchair, commode, cane, crutches, scooter, walker)
  - ☐ Bed or chair alarm

- ☐ Bed in low position
- ☐ Call light / personal items within reach
- ☐ Change in medication (e.g., timing or dosing of current medication)
- ☐ Non-slip floor mats
- ☐ Hip and/or joint protectors
- ☐ Non-slip footwear
- ☐ Patient and family education
- ☐ Patient sitting close to the nurses' station
- ☐ Physical/occupational therapy, includes exercise or mobility program
- ☐ Sitter
- ☐ Supplemental environmental or area lighting (when usual facility lighting is considered insufficient)
- ☐ Toileting regimen
- ☐ Visible identification of patient as being at risk for fall (e.g., Falling Star)
- ☐ None
- ☐ Unknown
- ☐ Other
    - Specify other precautions_____

- At the time of the fall, was the patient on medication known to increase the risk of fall?
    - ☐ Yes
        - Was the medication considered to have contributed to the fall?
            - Yes
            - No
            - Unknown
    - ☐ No
    - ☐ Unknown
- Did restraints, bedrails, or other physical device contribute to the fall (includes tripping over device electrical power cords)?
    - ☐ Yes
    - ☐ No
    - ☐ Unknown

TxHSN Preventable Adverse Event Reporting Questions Worksheet

SPECIFICS QP-- DEEP VEIN THROMBOSIS (DVT) OR PULMONARY EMBOLISM (PE) AFTER TOTAL KNEE REPLACEMENT OR AFTER HIP REPLACEMENT

- Which of the following occurred? (check all that apply)
  - ☐ Deep Vein Thrombosis (DVT)
    - What was the location of the DVT?
      - Upper extremity / upper thorax
      - Lower extremity / pelvis
      - Both
    - Which diagnostic test(s) confirmed the DVT? (check all that apply)
      - Venous compression ultrasound or duplex ultrasound
      - Magnetic resonance imaging (MRI)
      - Computed tomography (CT)
      - Venography
      - None of the above.
    - Prior to the onset of the VTE incident, was a formal VTE risk assessment documented?
      - Yes
      - No
        - Was the use of a VTE prophylaxis order set documented?
          - ☐ Yes
          - ☐ No
          - ☐ Unknown
      - Unknown
        - Was the use of a VTE prophylaxis order set documented?
          - ☐ Yes
          - ☐ No
          - ☐ Unknown
    - What was the patient's documented risk of VTE?
      - Low risk of VTE
      - High risk of VTE
        - Prior to the onset of the VTE incident, what was the documented risk of bleeding, if any?
          - ☐ At increased risk for bleeding
          - ☐ Not at increased risk for bleeding
          - ☐ Unknown
      - ☐ Unknown
    - Prior to the onset of the VTE incident was any physical or mechanical prophylaxis (e.g., graduated compression stockings, intermittent pneumatic compression device, venous foot pumps) applied?
      - Yes
      - No
      - Unknown
    - Prior to the onset of the VTE incident, was any pharmacological anticoagulant prophylaxis administered?
      - Yes [If this is selected STOP. This form is complete.]

- No
  - Which of the following best describes why the pharmacologic anticoagulant prophylaxis was not given? (check all that apply)
    - ☐ Contraindicated
    - ☐ Patient determined to be at low risk
    - ☐ Risk / benefit did not warrant prophylaxis
    - ☐ Patient refused
    - ☐ Unknown
    - ☐ Other
      - Specify other reason that Pharmacologic anticoagulant prophylaxis was not given_____

☐ Pulmonary Embolism (PE)

- Which diagnostic test(s) confirmed the PE? (check all that apply)
  - Chest CT angiography with contrast
  - Nuclear medicine pulmonary scan (ventilation / perfusion lung scan, V/Q scan, pulmonary scintigraphy)
  - Magnetic resonance imaging (MRI)
  - Pulmonary angiography
  - Post-mortem examination finding that PE likely contributed to death of patient
  - None of the above [If this is selected STOP. This form is complete.]
- Prior to the onset of the VTE incident, was a formal VTE risk assessment documented?
  - Yes
  - No
    - Was the use of a VTE prophylaxis order set documented?
      - ☐ Yes
      - ☐ No
      - ☐ Unknown
  - Unknown
    - Was the use of a VTE prophylaxis order set documented?
      - ☐ Yes
      - ☐ No
      - ☐ Unknown
- What was the patient's documented risk of VTE?
  - Low risk of VTE
  - High risk of VTE
    - Prior to the onset of the VTE incident, what was the documented risk of bleeding, if any?
      - ☐ At increased risk for bleeding
      - ☐ Not at increased risk for bleeding
      - ☐ Unknown
- Prior to the onset of the VTE incident was any physical or mechanical prophylaxis (e.g., graduated compression stocking, intermittent pneumatic compression device, venous foot pumps) applied?
  - Yes

- No
- Unknown

- Prior to the onset of the VTE incident, was any pharmacological anticoagulant prophylaxis administered?
  - Yes [If this is selected STOP. This form is complete.]
  - No
    - Which of the following best describes why the pharmacologic anticoagulant prophylaxis was not given? (check all that apply)
      - ☐ Contraindicated
      - ☐ Patient determined to be at low risk
      - ☐ Risk / benefit did not warrant prophylaxis
      - ☐ Patient refused
      - ☐ Unknown
      - ☐ Other
        - Specify other reason that pharmacologic anticoagulant prophylaxis was not given_____
  - Unknown [If this is selected STOP. This form is complete.]

TxHSN Preventable Adverse Event Reporting Questions Worksheet

SPECIFICS QP—STAGE III OR IV OR UNSTAGEABLE PRESSURE ULCER ACQUIRED AFTER ADMISSION/PRESENTATION TO A HEALTHCARE FACILITY

- What was the most advanced stage of the pressure ulcer being reported?
  - ☐ Stage / Category III
  - ☐ Stage / Category IV
  - ☐ Unstageable
  - ☐ Unknown [If this is selected then STOP, this form is complete]

- What was the status on admission of the Stage/Category III, IV, or unstageable pressure ulcer? (Select one)
  - ☐ Not present
  - ☐ Stage / Category I
  - ☐ Stage / Category II
  - ☐ Suspected Deep Tissue Injury [If this is selected then STOP, this form is complete]
  - ☐ Stage / Category III [If this is selected then STOP, this form is complete]
  - ☐ Stage / Category IV [If this is selected then STOP, this form is complete]
  - ☐ Unstageable [If this is selected then STOP, this form is complete]
  - ☐ Unknown
    - On admission to this facility, was a skin inspection documented?
      - Yes
      - No
      - Unknown
    - When was the first pressure ulcer risk assessment documented?
      - On admission (within 24 hours)
        - What type of risk assessment was documented?
          - ☐ Formal assessment (e.g., Braden, Braden Q (pediatric version), Norton, Waterlow)
          - ☐ Clinical assessment
          - ☐ Unknown
        - As a result of the assessment, was the patient documented to be at increased risk for pressure ulcer?
          - ☐ Yes
          - ☐ No
          - ☐ Unknown
      - Not on admission, but documented prior to the discovery of a newly-developed, or advancement of an existing pressure ulcer
        - What type of risk assessment was documented?
          - ☐ Formal assessment (e.g., Braden, Braden Q (pediatric version), Norton, Waterlow)
          - ☐ Clinical assessment
          - ☐ Unknown
        - As a result of the assessment, was the patient documented to be at increased risk for pressure ulcer?
          - ☐ Yes
          - ☐ No
          - ☐ Unknown
      - Not on admission, but documented after discovery of a newly-developed, or advancement of an existing pressure ulcer

- No risk assessment documented
- Unknown

- What intervention(s) was used? (check all that apply)
  - Pressure redistribution device
  - Repositioning
  - Hydration and/or nutritional support
  - Skin care practices to prevent moisture and shearing
  - Other
    - Specify other intervention(s) _____
  - None
  - Unknown
- What type of device or appliance was involved in the development or advancement of the pressure ulcer?
  - Anti-embolic device
  - Intraoperative positioning device
  - Orthopedic appliance (e.g., cast, splint, orthotic)
  - Oxygen delivery device (e.g., nasal prongs, oxygen mask)
  - Restraints
  - Tube
    - What type of tube?
      - ☐ Endotracheal
      - ☐ Gastrostomy
      - ☐ Nasogastric
      - ☐ Tracheostomy
      - ☐ Indwelling urinary catheter
      - ☐ Other
        - Specify other tube type_____
  - Other
  - Unknown
  - None

- During the patient's stay at this facility, did the patient develop a secondary morbidity (e.g., osteomyelitis, sepsis, tunneling, or fissure)?
  - Yes
    - Was the secondary morbidity attributed to the presence of the pressure ulcer?
      - ☐ Yes
      - ☐ No
      - ☐ Unknown
  - No
  - Unknown

TxHSN Preventable Adverse Event Reporting Questions Worksheet

SPECIFICS QP—SURGICAL SITE INFECTIONS FOLLOWING A SPINAL PROCEDURE, SHOULDER PROCEDURE, ELBOW PROCEDURE, LAPAROSCOPIC GASTRIC BYPASS, GASTROENTEROSTOMY, LAPAROSCOPIC GASTRIC RESTRICTIVE SURGERY, OR CARDIAC IMPLANTABLE ELECTRONIC DEVICE

See Specific Surgery/Invasive Procedure QP

- What is the patient's BMI? _____(Only appears in Gastric surgeries)
- Enter ICD code associated with this event (if available) _____
- What was the patient's documented American Society of Anesthesiologists (ASA) Physical Classification System class?
  - ☐ Class I
  - ☐ Class II
  - ☐ Class III
  - ☐ Class IV
  - ☐ Class V
  - ☐ ASA Classification was not documented
- Was the surgery performed as an emergency?
  - ☐ Yes
  - ☐ No
  - ☐ Unknown
- When was the event discovered?
  - ☐ Before anesthesia started or, if no anesthesia used, before procedure started
  - ☐ After anesthesia started, but before incision or start of procedure
  - ☐ After procedure started (incision), but before procedure ended (closure)
  - ☐ At closure, if surgical operation
  - ☐ After procedure ended, but before patient left operating room or other procedure area
  - ☐ During post-anesthesia care / recovery period
  - ☐ After post-anesthesia recovery, but before discharge
  - ☐ After patient was discharged
  - ☐ During anesthesia when no surgical operation or invasive procedure was performed
  - ☐ Unknown
- What was the medical or surgical specialty of the provider of team who performed the procedure?
  - ☐ Anesthesiology
  - ☐ Cardiology
  - ☐ Colorectal surgery
  - ☐ Dentistry, including oral surgery
  - ☐ Dermatology
  - ☐ Emergency medicine
  - ☐ Gastroenterology
  - ☐ Internal medicine
  - ☐ Neurological surgery
  - ☐ Obstetrics/Gynecology
  - ☐ Ophthalmology
  - ☐ Orthopedic surgery
  - ☐ Otolaryngology
  - ☐ Pediatrics
  - ☐ Pediatric surgery

- ☐ Plastic surgery
- ☐ Podiatry
- ☐ Pulmonology
- ☐ Radiology, including vascular and interventional
- ☐ Thoracic surgery
- ☐ Urology
- ☐ Vascular surgery
- ☐ Other
  - Specify other specialty_____

- Which best describes the event?
  - ☐ Surgical event
    - Which of the following best characterizes the surgical event?
      - Surgical site infection
        - The SSI was classified as which of the following?
          - ☐ Organ/space
          - ☐ Deep incisional primary (DIP)
          - ☐ Deep incisional secondary (DIS)
          - ☐ Superficial incisional primary (SIP)
          - ☐ Superficial incisional secondary (SIS)
          - ☐ Unknown
      - Bleeding requiring return to the operating room
      - Burn and/or operating room fire
        - Which of the following occurred?
          - ☐ Burn
          - ☐ Operating room fire
          - ☐ Both
      - Incorrect surgical or invasive procedure
        - What was incorrect about the surgical or invasive procedure?
          - ☐ Incorrect patient
          - ☐ Incorrect side
          - ☐ Incorrect site
          - ☐ Incorrect procedure
          - ☐ Incorrect implant by mistake
          - ☐ Incorrect implant because correct implant was not available
          - ☐ Other
            - Specify other incorrect action regarding surgical or invasive procedure_____
      - Unintended laceration or puncture
      - Dehiscence, flap or wound failure or disruption, or graft failure
      - Unintended blockage, obstruction, or ligation
      - Unplanned removal of organ
      - Other
        - Specify other characterization of event_____
  - ☐ Anesthesia event
    - If the event involved anesthesia, which of the following best characterizes the event?
      - Dental injury
      - Ocular injury

- Peripheral nerve injury
- Awareness (during anesthesia)
- Malignant hyperthermia
- Problem with anesthetic, medical gas, mediation, or other substance administration (Medication or Other Substance QP will follow)
- Problem with device used in the delivery of anesthesia (Device or Supply, Including Health Information Technology (HIT) will follow)
- Difficulty managing airway
    - Which of the following best characterizes the airway management problem?
        - ☐ Difficulty during tracheal intubation
        - ☐ Difficulty maintaining airway during procedure
        - ☐ Esophageal intubation
        - ☐ Re-intubation, following extubation, in the operating or recovery room
        - ☐ Other
            - Specify other characterization of airway management problem_____

☐ Major complication that could be associated with either surgery or anesthesia

- Which of the following major complications occurred?
    - Cardiac or circulatory event
    - Central nervous system event
    - Renal failure, impairment, or insufficiency
    - Respiratory failure, requiring unplanned respiratory support, within 24 hours after the procedure
        - Which of the following best describes the respiratory support provided?
            - ☐ Prolonged ventilator support
            - ☐ Re-institution of ventilator following discontinuation
            - ☐ Other
                - Specify other respiratory support_____
    - Other
        - Specify other complication_____

SPECIFICS QP—POOR GLYCEMIC CONTROL: DIABETIC KETOACIDOSIS, HYPOGLYCEMIC COMA, DIABETIC KETOACIDOSIS, NONKETONIC HYPEROSMOLARITY, SECONDARY DIABETES WITH KETOACIDOSIS OR SECONDARY DIABETES WITH HYPEROSMOLARITY

See Medication QP below.

SPECIFICS QP—PATIENT DEATH OR SEVERE HARM ASSOCIATED WITH CONTAMINATED DRUGS OR BIOLOGICS

See QP for Medication below

SPECIFICS QP—PATIENT DEATH OR SEVERE HARM ASSOCIATED WITH THE USE OF CONTAMINATED DEVICES

See QPs for Devices and Medication below

SPECIFICS QP—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.

See QPs for Devices and Medication below

SPECIFICS QP—PATIENT DEATH OR SEVERE HARM ASSOCIATED WITH A MEDICATION ERROR

See QP for Medication below

SPECIFICS QP—DEVICE OR SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)

- What type of device was involved in the event?
  - ☐ HIT device
    - Which of the following best characterizes the type of HIT device related to the event?
      - Administrative/billing or practice management system
        - Which component of the administrative/billing system?
          - ☐ Master patient index
          - ☐ Registration/appointment scheduling system
          - ☐ Coding/billing system
          - ☐ Unknown
          - ☐ Other
            - Specify other component of administrative / billing system_____
      - Automated dispensing system
      - Electronic health record (EHR) or component of EHR
        - Which type of component of the EHR?
          - ☐ Computerized provider order entry (CPOE) system
          - ☐ Pharmacy system
          - ☐ Electronic medication administration record (e-MAR)
          - ☐ Clinical documentation system (e.g., progress notes)
          - ☐ Clinical decision support (CDS) system
          - ☐ Unknown
          - ☐ Other
            - Specify other component of EHR _____
      - Human interface device (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)
      - Laboratory information system (LIS), including microbiology and pathology systems
      - Radiology/diagnostic imaging system, including picture archiving and communications system (PACS)
      - Other
        - Specify other type of HIT device related to the event_____
    - Which of the following best describes the circumstances involving the HIT device in the event?
      - Incompatibility between devices
      - Equipment /device function
        - Which problem(s) resulted from the equipment/device function problem? (check all that apply)
          - ☐ Loss or delay of data
          - ☐ System returns or stores data that does not match patient
          - ☐ Image measurement/corruption issue
          - ☐ Image orientation incorrect
          - ☐ Incorrect test results
          - ☐ Incorrect software programming calculation

- ☐ Incorrect or inappropriate alert
- ☐ Other
  - Specify other problem that resulted from the equipment / device function problem_____ _____

- Equipment/device maintenance
- Hardware failure or problem
- Network failure or problem
- Ergonomics, including human / device interface issue
  - Which ergonomics or human/device interface issue(s)? (check all that apply)
    - ☐ Hardware location (e.g., awkward placement for use)
    - ☐ Data entry or selection (e.g., entry or selection of wrong patient, wrong provider, wrong drug, wrong dose)
    - ☐ Information display or interpretation (e.g., font size, color of font, location of information in display screen)
    - ☐ Alert fatigue/alarm fatigue
    - ☐ Other
      - Specify other ergonomics or human / device interface issue_____
- Security, virus, or other malware issue
- Unexpected software design issue
- Unknown
- Other
  - Specify other circumstances involving the HIT device in the event _____

☐ Implantable device (e.g., device intended to be inserted into, and remain permanently in, tissue)

- At the time of the event, was the device placed within the patient's tissue? (Check one)
  - Yes
    - Did the event result in the device being removed? (Check one)
      - ☐ Yes
      - ☐ No
      - ☐ Unknown
  - No
  - Unknown

☐ Medical equipment (e.g., walker, hearing aid)

☐ Medical/surgical supply, including disposable product (e.g., incontinence supply)

- What is the name (brand or generic) of the device, product, software, or medical/surgical supply? _____

- What is the name of the manufacturer?_____
- Which of the following identifiers are known? (check all that apply)
  - ☐ Model number
    - What is the model number? _____
  - ☐ Software version
    - What is the software version? _____

- ☐ Firmware version
  - What is the firmware version? _____
- ☐ Serial number
  - What is the serial number? _____
- ☐ Lot or batch number
  - What is the lot or batch number? _____
- ☐ Other unique product identifier
  - What is the type of other unique product identifier? _____
  - What is the other unique product identifier? _____
- ☐ Date of expiration
  - What is the expiration date? __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
- ☐ Unique Device Identifier
  - What is the Unique Device Identifier (UDI)? _____
- ☐ Asset Tag
  - What is the asset tag number? _____
- ☐ No identifiers known

- Was a device intended for single use involved in the event or unsafe condition (including use of a reprocessed single-use device)?
  - ☐ Yes
    - Was a device intended for a single use reused in the event or unsafe condition?
      - Yes
      - No
      - Unknown
  - ☐ No
  - ☐ Unknown

TxHSN Preventable Adverse Event Reporting Questions Worksheet

SPECIFICS QP—MEDICATIONS

- What type of medication / substance was involved?
  - ☐ Medications
  - ☐ Biological products
  - ☐ Nutritional products
  - ☐ Expressed human breast milk
  - ☐ Medical gases (e.g., oxygen, nitrogen, nitrous oxide)
  - ☐ Contrast media
  - ☐ Radiopharmaceuticals
  - ☐ Patient food (not suspected in drug-food interactions)
  - ☐ Drug-drug, drug-food, or adverse drug reaction as a result of a prescription and/or administration of a drug and/or food prior to admission
  - ☐ Other
    - Specify other type of medication / substance_____
- Which of the following best characterizes the event? (This question defaults to Incorrect action)
  - ☐ Unsafe condition
  - ☐ Adverse reaction in patient to the administered substance without any apparent incorrect action
  - ☐ Unknown
  - ☐ Incorrect action (process failure or error) e.g., administering overdose or incorrect medication
    - What was the incorrect action (check all that apply)
      - Incorrect patient
      - Incorrect medication / substance
      - Incorrect dose(s)
        - Which best describes the incorrect dose(s)? (Check one)
          - ☐ Overdose
          - ☐ Underdose
          - ☐ Missed or omitted dose
          - ☐ Extra dose
          - ☐ Unknown
      - Incorrect route of administration
      - Incorrect timing
        - Which best describes the incorrect timing? (Check one)
          - ☐ Too early
          - ☐ Too late
          - ☐ Unknown
      - Incorrect rate
        - Which best describes the incorrect rate? (Check one)
          - ☐ Too quickly
          - ☐ Too slowly
          - ☐ Unknown
      - Incorrect duration of administration or course of therapy
      - Incorrect dosage form (e.g., sustained release instead of immediate release)
      - Incorrect strength or concentration
        - Which best describes the incorrect strength or concentration? (Check one)
          - ☐ Too high

- ☐ Too low
- ☐ Unknown

- Incorrect preparation, including inappropriate cutting of tablets, error in compounding, mixing, etc.
- Expired or deteriorated medication / substance
  - What was the expiration date?__ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
- Medication / substance that is known to be an allergen to the patient
  - Was there a documented history of allergies or sensitivities to the medication/substance administered?
    - ☐ Yes
    - ☐ No
    - ☐ Unknown
- Medication / substance that is known to be contraindicated for the patient
  - What was the contraindication (potential or actual interaction)?
    - ☐ Drug-drug
    - ☐ Drug-food
    - ☐ Drug-disease
    - ☐ Other
      - Specify other contraindication_____
- Incorrect patient / family action (e.g., self-administered error)
- Other Specify other incorrect action_____

- At what stage in the process did the event originate, regardless of the stage at which it was discovered?
  - ☐ Purchasing
  - ☐ Storing
  - ☐ Prescribing/ordering
  - ☐ Transcribing
  - ☐ Preparing
  - ☐ Dispensing
  - ☐ Administering
  - ☐ Monitoring
  - ☐ Unknown
  - ☐ Other
    - Specify other stage in the process _____
- Generic name or investigational drug name _____
  - ☐ Ingredient RXCUI (if known) _____
  - ☐ Brand name (if known) _____
  - ☐ Manufacturer (if known) _____
  - ☐ Strength or concentration of product _____
  - ☐ Clinical drug component RXCUI (if known) _____
  - ☐ Dosage form of product _____
  - ☐ Dose form RXCUI (if known) _____
    - Was this medication / substance prescribed for this patient?
      - Yes
      - No
    - Was this medication / substance given to this patient?
      - Yes
      - No