Report EHR Safety Event

- Do not include information that identifies individuals (providers, patients) or facilities.
- Please create a separate report for each event or hazard identified.

If this report relates to a previously reported incident, please provide Event ID: ____________________

What is Being Reported?

**Required Question.** Select One option and enter related information where requested.

<table>
<thead>
<tr>
<th>Incident: An EHR event that reached a patient, whether or not the patient was harmed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was there any evidence of harm to a patient at the time of this report?</td>
</tr>
<tr>
<td>Event date: Occurred: _______________ Discovered: _______________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Near Miss: An EHR event that is not believed to have reached a patient.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event date: Occurred: _______________ Discovered: _______________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Patient Issue: An incident or near miss that impacted staff, employee(s), visitor(s).</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ An incident that involved a person other than a patient (e.g., nurse, staff, practice).</td>
</tr>
<tr>
<td>☐ A near-miss that impacted a person other than a patient.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsafe Condition: A circumstance that increases the probability of an EHR event.</th>
</tr>
</thead>
</table>

Describe the EHR Event or Unsafe Condition

**Required Question.**

*Do not include information that identifies individuals (providers, patients) or facilities.*
EHR Product Information

**Required Question. Please provide as much information as possible.**

Manufacturer / Vendor (required):

Product Name (required):

Product Version: 
(e.g., v 11.1)

Product Module: 
(e.g. visit note, lab order)

**What Adverse Event Did or Could Result?**

**Required Question. Select all that apply.**

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Occurred during this event</th>
<th>Could have occurred (Unsafe Condition)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inability to capture, save, view, retrieve, perceive important data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data lost, delayed, misdirected, corrupted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mislabeling/misidentification (wrong diagnosis, procedure, provider, patient)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misinterpretation (ambiguous, misleading output)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order entry problem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication error (dose, form, route, time, recipient)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug contraindicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrong lab test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrong imaging test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other order entry problem:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Additional Adverse Events</th>
<th>Occurred during this event</th>
<th>Could have occurred (Unsafe Condition)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong treatment (diet, therapy, equipment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scheduling error (wrong time, wrong people, missing resources)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure error (procedure, site, process)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recall, follow-up, reminder failure (did not reach recipient, wrong recipient)</td>
<td></td>
<td></td>
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<tr>
<td>Messaging, notification, communication failure</td>
<td></td>
<td></td>
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<tr>
<td>Privacy, confidentiality breach</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other information problem:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Where Did The Event or Unsafe Condition Occur?

Required Question. Select one option and enter related information where requested.

- Office, clinic
  - Number of clinicians / practitioners: [ ]
  - This is a teaching facility: ○ Yes ○ No ○ Unknown

- Hospital
  - Number of beds: [ ]
  - Department / area:
    - ○ Inpatient general care area (e.g., Medical / surgical unit)
    - ○ Special care area (ICU, CCU, NICU)
    - ○ Labor and delivery
    - ○ Operating room or procedure area (cardiac catheter lab, endoscopy area) including PACU or recovery
    - ○ Radiology, imaging department, including onsite mobile units
    - ○ Pharmacy
    - ○ Laboratory, including pathology and blood bank
    - ○ Emergency department
    - ○ Other outpatient department
    - ○ Other clinical area within the facility
    - ○ Other non-clinical area within the facility
    - ○ Outside area (e.g., grounds of this facility)
    - ○ Unknown location in hospital
    - ○ Other hospital area: [ ]

- Is this a teaching facility: ○ Yes ○ No ○ Unknown

- Ambulatory surgery center
  - Is this a teaching facility: ○ Yes ○ No ○ Unknown

- Imaging center (non-hospital)

- Laboratory

- Nursing home, long-term care facility, transitional care facility (except LTAC)
  - Is this a teaching facility: ○ Yes ○ No ○ Unknown

- Pharmacy
  - Is this a teaching facility: ○ Yes ○ No ○ Unknown

- Private home

- Other location: [ ]

*Do not include information that identifies individuals (providers, patients) or facilities.*
What Do You Believe Caused the Problem?

Required Question. Check all that apply.

☐ Wrong information produced, retrieved, displayed:
  ☐ Auto-populated data
    ☐ Paste forward
    ☐ Template
    ☐ Pre-filled form
  ☐ Miscalculated field
    ☐ Biometrics (body weight, surface area, age)
    ☐ Lab result (GFR, creatinine clearance)
    ☐ Device output (PR interval, ejection fraction)
  ☐ Confusing screen, printer layout
  ☐ Multiple records open, viewed at the same time
  ☐ Data entered by system into wrong field

☐ Software malfunction (programming)

☐ User malfunction, slip, lapse:
  ☐ Wrong selection of drop-down menu or checkbox
  ☐ Data entered in wrong field
  ☐ Misinterpretation, misreading of screen, instruction, label, content
  ☐ Deliberate sabotage, vandalism

☐ User training, supervision

☐ Alarm, alert, reminder neutralized, disabled, disregarded, canceled

☐ Product configuration, installation

☐ Workload, fatigue, distraction, impairment

☐ Interference with, by another system (hacking, virus, software conflict)

☐ Power failure

☐ Hardware failure, damage

☐ Communication, network, data exchange failure

☐ Security authorization failure

☐ Other cause: ____________________________

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☐ Unknown

Who Was Using The System at The Time Of The Event?

Select one option and enter related information where requested.

☐ Licensed healthcare professional (or trainee):
  ☐ Physician / Dentist
    ☐ Student
    ☐ House Officer
  ☐ Nurse, Nurse Practitioner, Physician Assistant
    ☐ Student
  ☐ Pharmacist, Pharmacy Technician
    ☐ Student
  ☐ Allied Health Professional, Paramedic
    ☐ Student

☐ Unlicensed healthcare worker (or trainee), including clerical / administrative personnel, technical / laboratory personnel

Title, job designation: ____________________________

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☐ Emergency service personnel

☐ Information technology personnel

☐ Other user: ____________________________

Do not include information that identifies individuals (providers, patients) or facilities.

☐ Unknown user

☐ No user or not applicable
Was an Intervention Required by an Information Technologist?
Select one option and enter related information where requested.

☐ Yes

☐ Check all that apply.

☐ Restore data from back-up
☐ Repair, re-program
☐ Bug fix
☐ Training
☐ Work with paper temporarily
☐ Substitute a different software system temporarily
☐ Replace hardware
☐ Install a different system

☐ No

If a “Near Miss” Resulted, What Kept it from Reaching a Person (Patient or Other)?
Check all that apply.

☐ Fail-safe designed into the process and / or safeguard worked effectively
☐ Practitioner or staff who made the error noticed and recovered from the error (avoiding any possibility of it reaching the patient)
☐ Spontaneous action by a practitioner or staff member (other than person making the error) prevented the event from reaching the patient
☐ Action by the patient or patient’s family member prevented the event from reaching the patient
☐ Other reason: [ ]

☐ Unknown

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Was the Event Associated with Handover/Handoff?
Select one option.

☐ Yes
☐ No
☐ Unknown
Are Any Contributing Factors to the Event Known?

Select one option and enter related information where requested.

- Yes
  - Please check all factors that contributed to the event.
    - Environment
      - Culture of safety, management
      - Physical surroundings (e.g., lighting, noise)
    - Staff Qualifications
      - Competence (e.g., qualifications, experience)
      - Training
    - Supervision / Support
      - Clinical supervision
      - Managerial supervision
    - Policies and Procedures, including Clinical Protocols
      - Presence of policies
      - Clarity of policies
    - Equipment / Device
      - Function
      - Design
      - Availability
      - Maintenance
    - Data
      - Availability
      - Accuracy
      - Legibility
    - Communication
      - Supervisor to staff
      - Among staff or team members
      - Staff to patient (or family)
    - Human Factors
      - Fatigue
      - Stress
      - Inattention
      - Cognitive factors
      - Health issues
  - Other (please specify):

- No
- Unknown

Did the Event Result in a National Quality Forum (NQF) Serious Reportable Event?

Select one option.

- Yes
- No
- Unknown

How Preventable Was the Incident?

Select one option.

- 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
Notwithstanding the event you are reporting, has the adoption and use of an EHR by your practice added to patient safety, improved care or improved documentation?

Select one option.

- Yes, definitely
- Likely
- Not sure
- No impact

Report and Event Reporter Information

**Required Question.** Please provide as much information as possible.

Report Date: __________________________

Name: __________________________

First (required)  Middle  Last (required)

Contact Information (at least one of Email or Phone is required):

Email: __________________________

If you provide an email address, we can send you reports and other information related to your event as it becomes available. Your email will not be used for any other purpose.

Phone: __________________________ - __________________________ - Ext. __________________________

PDR Secure needs a means of contacting you. If you change your email address regularly, or if you are uncomfortable providing your email address, please enter a phone number.

Job title: __________________________

Identity Share Authorization (required):

- I authorize PDR Secure to share my identity with the EHR vendor and/or the FDA, in conjunction with this report.
- I do not authorize PDR Secure to share my identity with any third party.

☐ I am ready to submit this report. I confirm that this report does not contain information that identifies individuals (providers, patients) or facilities.

(Required)
Additional Incident Information

Complete this section if you are reporting an Incident (an EHR event that reached a patient, whether or not the patient was harmed).

At the Time of the Event, What Was the Patient's Age?

Select one option.

- 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 (75-85 years)
- Aged Adult (>85 years)
- Unknown

Is the Patient’s Ethnicity Hispanic or Latino?

Select one option.

- Hispanic or Latino
- Not Hispanic or Latino
- Unknown

What is the Patient’s Race?

Select one option.

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- More than one Race
- Unknown

What Was the Extent of Harm That Resulted?

Required Question. Select one option.

- Death.
  Death at the time of assessment.
- Severe Permanent Harm.
  Sever lifelong body or psychological injury or disfigurement that interferes significantly with functional ability or quality of live. Prognosis at time of assessment.
- Permanent Harm.
  Lifelong bodily or psychological injury or increased susceptibility to disease. Prognosis at time of assessment.
- Temporary Harm.
  Bodily or psychological injury, but likely not permanent. Prognosis at time of assessment.
- Additional Treatment.
  Injury limited to additional intervention during admission or encounter, and/or increased length of stay but no other injury. Treatment since discovery, and/or expected treatment in future as direct result of event.
- Emotional Distress or Inconvenience.
  Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing; including phlebotomy and/or imaging studies). Distress / inconvenience since discovery, and/or expected in future as a direct result of the event.
- No Harm.
  Event reached patient, but no harm or distress resulted.
- Unknown.
Approximately When After the Discovery of the Incident was Harm Assessed?
Select one option.
- Within 24 hours
- After 24 hours but within three days
- Three days or later
- Unknown

Was an Intervention Attempted in Order to “Rescue” the Patient (i.e., to prevent, to minimize, or reverse harm)?
Select one option and enter related information where requested.
- Yes
  - Transfer, including transfer to a higher level care area within facility, transfer to another facility, or 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 intervention
  - Respiratory support (i.e., ventilation, tracheotomy)
  - Blood transfusion
  - Counseling or psychotherapy
  - Unknown
  - Other intervention (please specify):
- No
- Unknown

Did, or Will, the Incident Result in an Increased Length of Stay?
Select one option.
- Yes
- No
- Unknown

After the Discovery of the Incident, was the Patient, Patient’s Family, or Guardian, Notified?
Select one option.
- Yes
- No
- Unknown