Reversal Agent Incident Report Initiative

Incident report to be completed for the following reversal agents: naloxone (Narcan), flumazenil (Romazicon) and prothrombin complex concentrate, 4-factor, unactivated (Balfaxar, Kcentra)

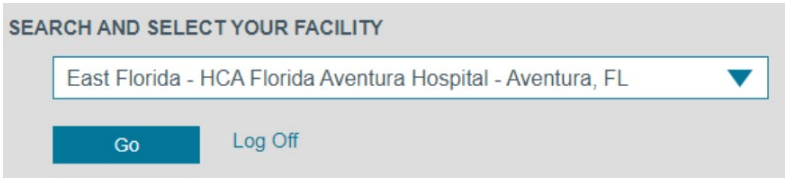
Opioid reversal	Benzodiazepine reversal	Vitamin K antagonist (warfarin) reversal Direct factor Xa inhibitor (e.g. apixaban, rivaroxaban) reversal
Naloxone (Narcan)	**Flumazenil (Romazicon)**	**Prothrombin complex concentrate, 4-factor, unactivated (Balfaxar, Kcentra)**

How to enter an incident report?

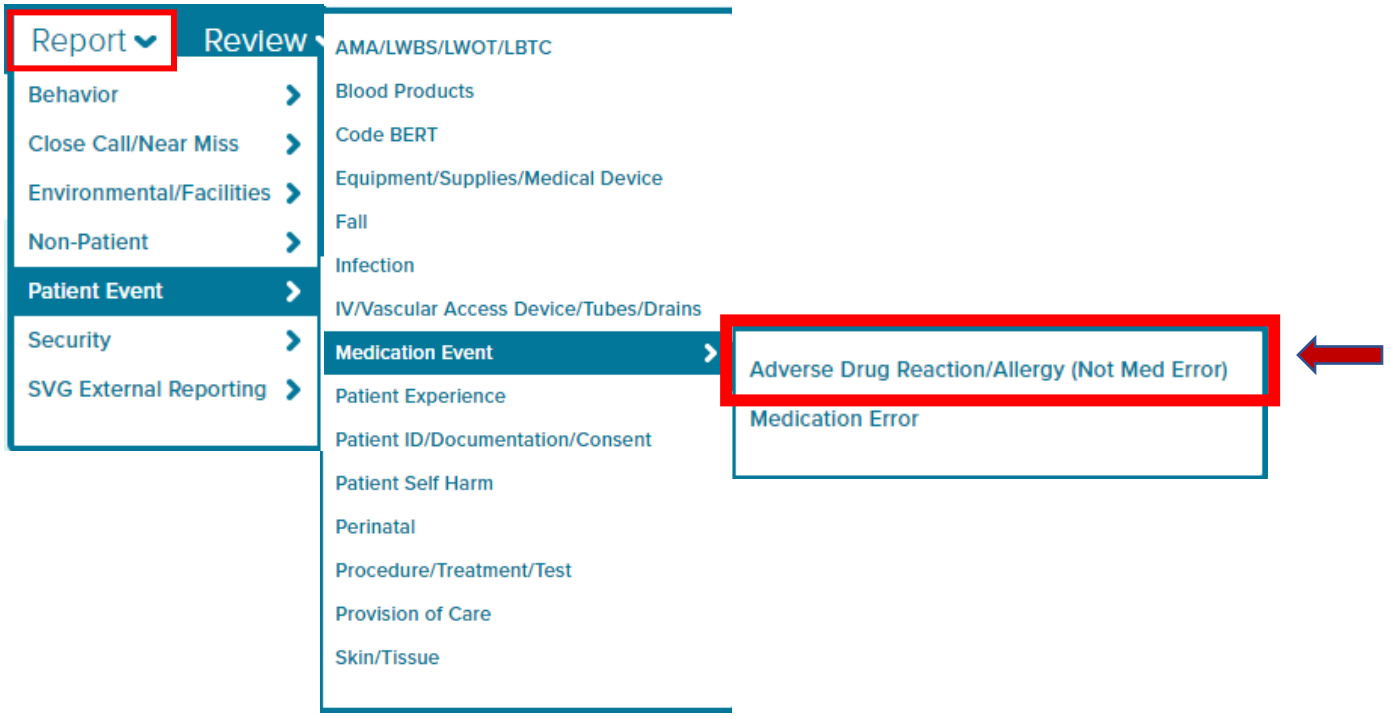
Step 1: Intranet Home Page → Scroll to the bottom right hand corner

Step 2: Click on ▫ Vigilanz Safety Event Reporting

Step 3: Select Facility



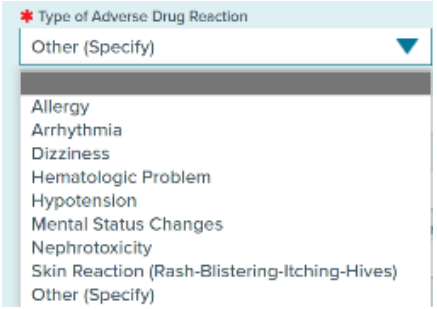
Step 4:



Information Required in the Incident Report:

Complete all blanks with red asterisks *

Type of Adverse Drug Reaction



Hartwig Scale (likely one from level 3 to level 7)

Mild (Level 1) The ADR Required No Change in the treatment with the Suspected Drug
Mild (Level 2) The ADR Required that the Suspected Drug be Withheld/Discontinued or Otherwise Changed – No Antidote or Other Treatment Required
Moderate (Level 3) The ADR Required that the Suspected Drug be Withheld/Discontinued or Otherwise Changed and/or an Antidote or Other Treatment is Required
Moderate (Level 4) Any Level 3 ADR that increases the Length of Stay by at Least One Day or the ADR is the Reason for Admission
Severe (Level 5) Any Level 4 ADR that Requires Intensive Medical Care
Severe (Level 6) The ADR Causing Permanent Harm to the Patient
Severe (Level 7) The ADR Either Directly or Indirectly Leading to the Death of the Patient

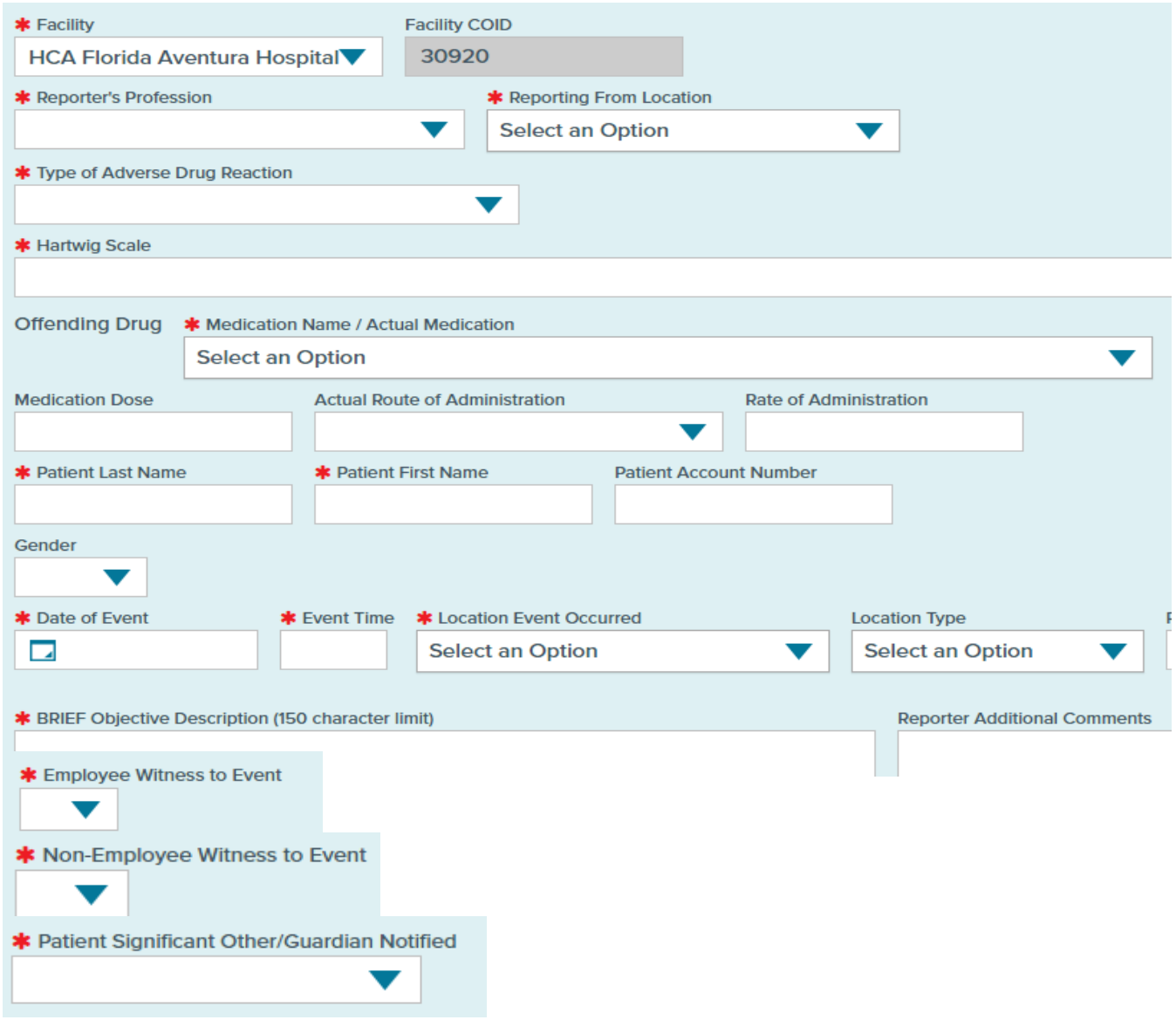
Offending Drug: Which opioid, anticoagulant or benzodiazepine was involved?

Brief objective description: Medication that caused the use of the reversal agent. Sign and symptoms noted before reversal agent administration. Resolution of signs and symptoms after the reversal agent was administered? Notification of the incident to attending physician?

Patient Example:
Patient over-sedated after administering lorazepam. Physician entered an order for flumazenil. Patient responded; patient now alert and oriented. Informed physician

Information Required in the Incident Report:

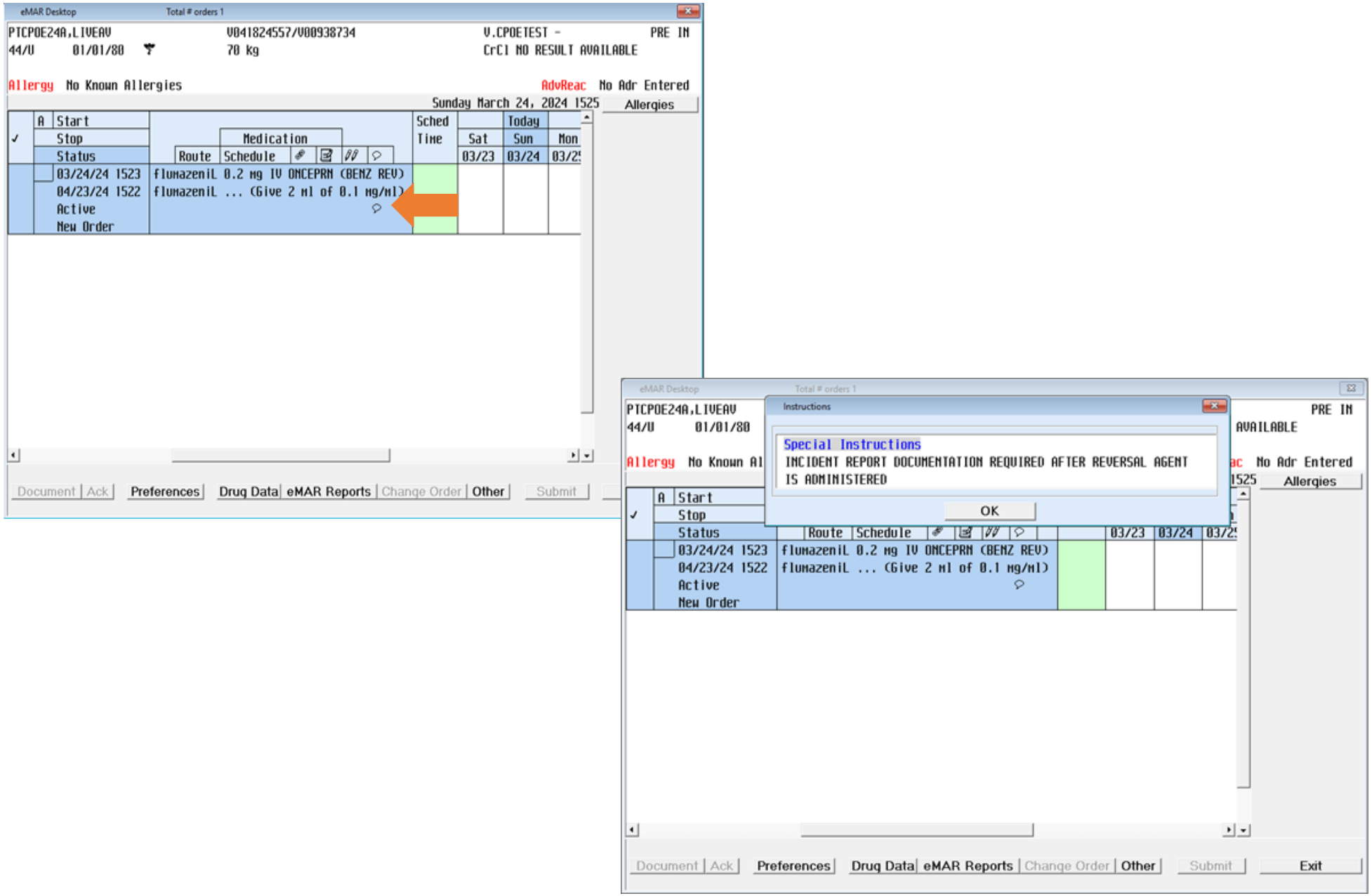
Complete all blanks with red asterisks *



Reversal Agent Incident Report Meditech Alert

Meditech alert for nursing reminding them to follow up with incident report.

Example of Meditech screen:



Reversal Agent Incident Report Meditech Alert

Meditech alert for provider entering the order reminding them to follow up with incident report.

Example of Meditech screen: