Patient Safety Event Workflow (To Be)

<table>
<thead>
<tr>
<th>Reporter</th>
<th>Reviewer(s)</th>
<th>Sender</th>
<th>Patient Safety Organization (PSO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Occurs</td>
<td>Report?</td>
<td>Log into System (e.g. EHR)</td>
<td>Generate form in appropriate PSO format</td>
</tr>
<tr>
<td>Yes</td>
<td>Log into System (e.g. EHR)</td>
<td>Log into Risk Management Information System (RMIS)</td>
<td>Receive and process the form</td>
</tr>
<tr>
<td>No</td>
<td>End Process</td>
<td>Event Occurs</td>
<td>End Process</td>
</tr>
<tr>
<td>Yes</td>
<td>Request Event Report</td>
<td>Retrieve the form</td>
<td>End Process</td>
</tr>
<tr>
<td>No</td>
<td>End Process</td>
<td>Evaluate Form and Determine Appropriate Procedures &amp; Refine Form Responses</td>
<td>Form continuing on to NPSD is out of scope for this WG</td>
</tr>
<tr>
<td>Yes</td>
<td>Retrieve Patient Record</td>
<td>Form Complete?</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>End Process</td>
<td>Yes</td>
<td>Form continuing on to NPSD is out of scope for this WG</td>
</tr>
<tr>
<td>Yes</td>
<td>Retrieve and pre-populate* Form from Form Repository</td>
<td>Confirm / Sign Off that form is ready to send</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>End Process</td>
<td>Yes</td>
<td>Form continuing on to NPSD is out of scope for this WG</td>
</tr>
<tr>
<td>Yes</td>
<td>Auto-populate* Form from EHR</td>
<td>Send Form?</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>End Process</td>
<td>Yes</td>
<td>Form continuing on to NPSD is out of scope for this WG</td>
</tr>
<tr>
<td>Yes</td>
<td>Complete the Form</td>
<td>End Process</td>
<td>End Process</td>
</tr>
<tr>
<td>No</td>
<td>End Process</td>
<td>End Process</td>
<td>End Process</td>
</tr>
</tbody>
</table>

* Where functionality is available
Adverse Event Workflow (Voluntary Reporting (Rx) – Within Clinical Setting)

**Reporter/Reviewer/Sender**

1. Adverse Event Occurs
   - Report the event?
     - Yes → End Process
     - No → Log into EHR System

2. Logged in to EHR?
   - Yes → Retrieve Patient Record
   - No → Log into EHR System

3. Discontinue Rx due to adverse event?
   - Yes → Request the voluntary AE reporting form from the form repository
   - No → Optional: Triggered by the EHR

4. Render the pre-populated form

5. Complete the form

6. Submit the completed form

7. Receive Email Acknowledgement

**FDA**

1. Receive and process the electronic form
   - Acknowledgement sent back to the sender

2. End Process

* whether the adverse event might be related to the drug, what adverse events are expected (or known), is this adverse event different even if expected and non-serious, etc
Adverse Event Workflow (Voluntary Reporting (Rx) – Inpatient)

Reporter (Healthcare Provider)

- Adverse Event Occurs
  - Yes
    - Log into System (e.g. EHR)
    - Retrieve Patient Record
    - Discontinue Rx due to adverse event?
      - Yes
        - Request the voluntary AE reporting form from the form repository
        - Render and pre-populate Form from Form Repository
        - Auto-populate Form from EHR
        - Complete the form
        - Submit to Voluntary Patient Safety Reporting System
        - Submit to RMS?
          - Yes
            - To PSE Workflow
          - No
            - Send Completed form to FDA
      - No
        - Log in to EHR?
          - Yes
            - Retrieve Patient Record
          - No
            - Log into System (e.g. EHR)
  - No

Reviewer(s)/Sender

- Receive form
  - Review, Categorize and Process the Event
    - Yes
      - Report Event to FDA
      - Complete Form (Render and pre-populate Form from Form Repository)
      - Send SDC Standard Form
      - Receive Acknowledgement
      - Report to PSO?
        - Yes
          - End Process
        - No
          - Send SDC Standard Form
  - No
    - End Process

FDA

- Receive and process the form
  - Yes
    - Receive and process the form
    - Send Acknowledgement to Sender
  - No
    - End Process

Patient Safety Organization (PSO)

- Receive and process the form
Adverse Event Workflow (Mandatory Reporting (Device) – Inpatient-MedSun Hospitals)

Report Cycle:

**Reporter (Healthcare Provider)**

- **All device reports**
  - **Logged in to EHR?**
    - **Yes**
      - **Log into System [e.g. EHR]**
    - **No**
  
- **Retrieve Patient Record**

- **Report due to adverse event?**
  - **Yes**
    - **Request the mandatory AE reporting form from the form repository**
  
- **Render and pre-populate Form from Form Repository**

- **Auto-populate Form from EHR**

- **Complete the form**

- **Submit to RMIS?**
  - **Yes**
    - **MedSun Hospital?**
      - **Yes**
        - **Send Completed form to FDA**
      - **No**
        - **To PLE Workflow**
  
- **No**

**Reviewer / Sender**

- **Receive form**

- **Send to FDA?**
  - **Yes**
    - **Send to Manufacturer?**
      - **Yes**
        - **End Process**
      - **No**
        - **End Process**
  
- **No**

**Manufacturer**

- **Receive and process the form**

**FDA**

- **Receive and process the form**

Note: This reporting process may take place in parallel or sequential to the Patient Safety Event Reporting process where submission occurs to the PSO.