Event ID: _____

Initial Report Date (HERF Q1): _____

Patient Safety Event Report – Hospital:

H MEDICATION OR OTHER SUBSTANCE

Use this form to report any patient safety event or unsafe condition involving a substance such as a medications, biological products, nutritional products, expressed human breast milk, medical gases, or contrast media. Do not complete this form if the event involves appropriateness of therapeutic choice or decision making (e.g., physician decision to prescribe medication despite known drug-drug interaction). If the event involves a device, please also complete the Device or Medical/Surgical Supply including Health Information Technology (HIT) form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What type of medication/substance was involved? CHECK ONE:

a. ☐ Medications

2. What type of medication?
CHECK ONE:

a. ☐ Prescription or over-the-counter (including herbal supplements)
b. ☐ Compounded preparations
c. ☐ Investigational drugs
d. ☐ Unknown

3. Please list all ingredients:

_____

_____

_____

_____

b. ☐ Biological products

4. What type of biological product?
CHECK ONE:

a. ☐ Vaccines
b. ☐ Other biological products (e.g., thrombolytic)

5. What was the lot number of the vaccine?

_____
LOT NUMBER

c. ☐ Nutritional products

6. What type of nutritional product?
CHECK ONE:

a. ☐ Dietary supplements (other than vitamins or minerals)
b. ☐ Vitamins or minerals
c. ☐ Enteral nutritional products, including infant formula
d. ☐ Parenteral nutritional products
e. ☐ Other: **PLEASE SPECIFY** _____

d. ☐ Expressed human breast milk

e. ☐ Medical gases (e.g., oxygen, nitrogen, nitrous oxide)

f. ☐ Contrast media

g. ☐ Radiopharmaceuticals
h. ☐ Patient food (not suspected in drug-food interactions)
i. ☐ 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

j. ☐ Other substance: **PLEASE SPECIFY** _____

STOP This form is complete.

7. Which of the following best characterizes the event? CHECK ONE:

a. ☐ Incorrect action (process failure or error) (e.g., such as administering overdose or incorrect medication)

b. ☐ Unsafe condition → ANSWER QUESTIONS 17 - 25

c. ☐ Adverse reaction in patient to the administered substance without any apparent incorrect action

d. ☐ Unknown → STOP This form is complete.

8. What was the incorrect action? CHECK ALL THAT APPLY:

a. ☐ Incorrect patient

b. ☐ Incorrect medication/substance

c. ☐ Incorrect dose(s)

9. Which best describes the incorrect dose(s)? CHECK ONE:

a. ☐ Overdose
b. ☐ Underdose
c. ☐ Missed or omitted dose
d. ☐ Extra dose
e. ☐ Unknown

d. ☐ Incorrect route of administration

e. ☐ Incorrect timing

10. Which best describes the incorrect timing? CHECK ONE:

a. ☐ Too early
b. ☐ Too late
c. ☐ Unknown

f. ☐ Incorrect rate

11. Which best describes the incorrect rate? CHECK ONE:

a. ☐ Too quickly
b. ☐ Too slowly
c. ☐ Unknown

g. ☐ Incorrect duration of administration or course of therapy

h. ☐ Incorrect dosage form (e.g., sustained release instead of immediate release)

i. ☐ Incorrect strength or concentration

12. Which best describes the incorrect strength or concentration? CHECK ONE:

a. ☐ Too high
b. ☐ Too low
c. ☐ Unknown

j. ☐ Incorrect preparation, including inappropriate cutting of tablets, error in compounding, mixing, etc.

k. ☐ Expired or deteriorated medication/substance

13. What was the expiration date? __ __ / __ __ / __ __ __ __
MM DD YYYY

l. ☐ Medication/substance that is known to be an allergen to the patient

14. Was there a documented history of allergies or sensitivities to the medication/substance administered? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

m. ☐ Medication/substance that is known to be contraindicated for the patient

15. What was the contraindication (potential or actual interaction)? CHECK ONE:

a. ☐ Drug-drug
b. ☐ Drug-food
c. ☐ Drug-disease
d. ☐ Other: **PLEASE SPECIFY** _____

n. ☐ Incorrect patient/family action (e.g., self-administration error)

o. ☐ Other: **PLEASE SPECIFY** _____

16. At what stage in the process did the event originate, regardless of the stage at which it was discovered?

CHECK ONE:

a. ☐ Purchasing
b. ☐ Storing
c. ☐ Prescribing/ordering
d. ☐ Transcribing
e. ☐ Preparing
f. ☐ Dispensing
g. ☐ Administering
h. ☐ Monitoring
i. ☐ Unknown
j. ☐ Other: **PLEASE SPECIFY**

_____

QUESTIONS 17 - 27 DO NOT APPLY TO COMPOUNDED PREPARATION OR EXPRESSED HUMAN BREAST MILK

FOR AN INCIDENT, ANSWER QUESTIONS 17-27

FOR A NEAR MISS, ANSWER QUESTIONS 17-26

FOR AN UNSAFE CONDITION, ANSWER QUESTIONS 17-25

Please provide the following medication details for any medications or other substances directly involved in the event.

	17. Generic name or investigational drug name	18. Ingredient RXCUI (if known)	19. Brand name (if known)	20. Brand name RXCUI (if known)	21. Manufacturer (if known)	22. Strength or concentration of product
1						
2						
3						
4						
5						

	23. Clinical drug component RXCUI (if known)	24. Dosage form of product	25. Dose form RXCUI (if known)	26. Was this medication/ substance prescribed for this patient?	27. Was this medication / substance given to this patient?
1				a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
2				a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
3				a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
4				a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
5				a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No

IF THIS EVENT DID NOT INVOLVE AN INCORRECT ROUTE OF ADMINISTRATION

STOP **This form is complete.**

IF THE EVENT INVOLVED AN INCORRECT ROUTE OF ADMINISTRATION, ANSWER QUESTIONS 28 - 29

28. What was the intended route of administration? CHECK ONE:

- a. ☐ Cutaneous, topical application, including ointment, spray, patch
- b. ☐ Subcutaneous
- c. ☐ Ophthalmic
- d. ☐ Oral, including sublingual or buccal
- e. ☐ Otic
- f. ☐ Nasal
- g. ☐ Inhalation
- h. ☐ Intravenous
- i. ☐ Intramuscular
- j. ☐ Intrathecal
- k. ☐ Epidural
- l. ☐ Gastric
- m. ☐ Rectal
- n. ☐ Vaginal
- o. ☐ Unknown
- p. ☐ Other: **PLEASE SPECIFY** _____

29. What was the actual route of administration (attempted or completed)? CHECK ONE:

- a. ☐ Cutaneous, topical application, including ointment, spray, patch
- b. ☐ Subcutaneous
- c. ☐ Ophthalmic
- d. ☐ Oral, including sublingual or buccal
- e. ☐ Otic
- f. ☐ Nasal
- g. ☐ Inhalation
- h. ☐ Intravenous
- i. ☐ Intramuscular
- j. ☐ Intrathecal
- k. ☐ Epidural
- l. ☐ Gastric
- m. ☐ Rectal
- n. ☐ Vaginal
- o. ☐ Unknown
- p. ☐ Other: **PLEASE SPECIFY** _____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 10/31/2014**