REQUIRED REPORTING OF SERIOUS ADVERSE EFFECTS TO FDA MEDWATCH

Emergency Support Function (ESF)	#8 – Public Health & Medical	Effective	13 JANUARY 2021
Relevant Section(s)	Operations / Medical Surge Branch	Next Review Date	JANUARY 2022

PURPOSE: To provide clear guidance on the required reporting of serious adverse effects to the FDA MedWatch.

TERMS: All instances involving medication errors and/or serious adverse effects due to an infusion must be reported to the FDA Watch within seven (7) calendar days of onset.

- For situations involving medication errors and/or adverse effects at fixed infusion sites or while Mobile Infusion Strike Team personnel are still present at a facility:
  - Required information will be provided to the Medical Surge Branch for forwarding as delineated below
- In anticipation of situations involving adverse effects to infusion therapy after the patient has departed from a fixed infusion site and/or after Mobile Infusion Strike Team personnel have departed from a facility, the following actions will be taken:
  - Patients at a fixed infusion site will be advised to contact their medical provider if and/or as soon as an adverse effect occurs, clearly informing the patient to contact 911 should the effects warrant
  - Patient(s) and staff at the nursing or other facilities where Mobile Infusion Strike Team personnel have provided infusion therapy should be advised of their responsibility to report adverse reactions to the appropriate medical provider for subsequent reporting.
    - Ideally, the particular provider that requested the infusion treatment should be the person to be advised, as well as the person to report such incidents
    - An informational and guidance sheet regarding FDA FedWatch will be provided to the staff member prior to Mobile Infusion Strike Team departure

Reporting by Fixed Infusion Site and/or Mobile Infusion Strike Team Personnel

Reporting of serious adverse effects due to an infusion will be based on the following:

- Serious Adverse Events defined as:
  - Death
  - Life-threatening adverse event
  - Inpatient hospitalization or prolongation of existing hospitalization
  - Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - Congenital anomaly/birth defect;
  - Medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.
- Information to be submitted will be specific to the particular medication infused on the patient of concern, e.g.,
  - Regeneron (Casirivimab or Imdevimab) or
  - Bamlanivimab
- Appropriate submittal of the report will be based on providing as much information as possible for the data fields on the following document:
  - "Med Watch The FDA Safety Information and Adverse Event Reporting Program," Form FDA 3500 (2/19)
    - A PDF copy of the document is attached to this protocol
    - Additionally, the document can be found at:
      - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf

Medical Surge Branch

Upon receipt of the appropriate information, the Medical Surge Branch will submit the necessary information as follows:

- Regeneron
  - Submit report online to www.fda.gov/medwatch/report.htm
  - In addition, please provide a copy of all FDA MedWatch forms to:
    - Regeneron Pharmaceuticals, Inc.
    - Fax: 1-888-876-2736
    - E-mail: medical.information@regeneron.com
    - Or call Regeneron Pharmaceuticals at 1-844-734-6643 to report adverse events.
- Bamlanivimab
  - Submit report online to www.fda.gov/medwatch/report.htm
  - In addition, please provide a copy of all FDA FedWatch forms to:
    - Eli Lilly and Company, Global Patient Safety
    - Fax: 1-317-277-0853
    - E-mail: mailindata_gsmtindy@lilly.com
    - Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921)
- Additionally, the Medical Surge Branch will ensure:
  - The patient information form specific to each patient infused by Mobile Infusion Strike Team personnel is updated to reflect information in the Adverse Effects text box.