TEXAS Health and Human Services | Texas Department of State Health Services

Clear Form

Report of Serious Adverse Drug Reaction Resulting in Therapeutic Changes, Hospitalization, or Death

Patient Information

Name	Date of Birth	Sex	Weight

Race (Check all that apply)

Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White Non-Hispanic ☐

White Hispanic ☐ American Indian or Alaskan Native ☐

Adverse Event (Check all that Apply)

Death ☐	Hospitalization ☐	Change of Therapy ☐	**Date of event:**

Briefly Describe Event and Current Patient Status:

Relevant Labs/Including Date:

Suspect Drug(s)

Name	Strength/Dose	Drug Start Date	Lot Number	NDC/Manufacturer

Other:

Prescriber Information

Prescribing Physician	Hospital	Treating Physician

Local or Regional Health Department Contact

Name of person filling out form		Local or Regional Health Department Name, Address	
Phone #	Job Title		Email

Pharmacy Staff Only

Send To FDA ☐	Date
No FDA Form Needed ☐	Date

Fax completed form within two (2) days of adverse event to:
DSHS Pharmacy Branch Fax # (512) 776-7489, Phone # (512) 776-7500