STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
310 Great Circle Road
NASHVILLE, TENNESSEE 37243

Memo

To: TennCare Providers
From: Bureau of TennCare
Date: August 12, 2016
Re: Important Voluntary Manufacturer Recall Information Regarding the Following Agents:

- **All Liquid Drug-Dietary Products** (PharmaTech)
- **Amikacin Sulfate Injection USP** (Teva Pharmaceuticals): 250 mg/mL, 2mL & 4mL vials

Liquid Drug-Dietary Products

PharmaTech is voluntarily recalling **all** liquid products due to a potential risk of product contamination with Burkholderia cepacia. The recall is due to contamination with Burkholderia cepacia.

This recall affects all liquid products from October 20, 2015 through July 15, 2016. Please see the following link for a complete list of affected products: http://www.fda.gov/Safety/Recalls/ucm515610.htm

PharmaTech, LLC is notifying its distributors and customers by recall letter and is arranging for return of all recalled products. Consumers, pharmacies, and healthcare facilities that have product which is being recalled should stop using and dispensing them immediately. Consumers with questions regarding this recall should contact Angelina Reyburn, Recall Coordinator at (754) 701-8320, Monday through Friday 8a – 5p EST. Consumers can contact their physician or healthcare provider if they have additional questions about these products.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
- Regular Mail or Fax: Download form: www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-address form, or submit by fax to 1-800-FDA-0178.

Additional Links:
FDA Communication:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm515625.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
PharmaTech LLC Communication: http://www.fda.gov/Safety/Recalls/ucm515610

Amikacin Sulfate Injection Vials

Teva Pharmaceuticals announced a voluntary recall of seven lots of Amikacin Sulfate Injection USP, 500 mg/2mL

(250 mg/mL) and 1 gram/4mL (250 mg/mL) vials due to the potential for the presence of glass particulate matter. The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected.

Amikacin Sulfate Injection 250 mg/mL, 2 mL & 4 mL vials were distributed nationwide through wholesalers, retailers, and pharmacies.

Teva issued an Urgent Drug Recall Letter to their direct customers. Teva is arranging for impacted product to be returned to Inmar. Anyone with an existing inventory of the recalled lot(s) should stop use and distribution, and quarantine the product immediately. Customers should notify all retail and medical facility accounts. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities. For medical related questions please contact Teva Medical Information at 888-838-2872, option 3, then, option 4. For a customer service related question, please contact Teva Customer Service at 800-545-8800, Monday – Friday; 8:00 AM – 5:00 PM EST. Consumers should immediately contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
- Regular Mail or Fax: Download form: www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-address form, or submit by fax to 1-800-FDA-0178.

Impacted Lots:

Lot #	Exp. Date	Strength	Vial Size	NDC# (Individual Pack)	NDC# (Shelf Pack - carton of 10 vials)
2381114	11/2016	1 gm/4 mL (250 mg/mL)	4 mL	0703-9040-01	0703-9040-03
2771114	11/2016	1 gm/4 mL (250 mg/mL)	4 mL	0703-9040-01	0703-9040-03
4760915	9/2017	1 gm/4 mL (250 mg/mL)	4 mL	0703-9040-01	0703-9040-03
7080315	3/2017	500 mg/2 mL (250 mg/mL	2 mL	0703-9032-01	0703-9032-03
7400315	3/2017	500 mg/2 mL (250 mg/mL)	2 mL	0703-9032-01	0703-9032-03
7410315	3/2017	500 mg/2 mL (250 mg/mL)	2 mL	0703-9032-01	0703-9032-03
7980415	4/2017	500 mg/2 mL (250 mg/mL)	2 mL	0703-9032-01	0703-9032-03

Additional Links:

FDA Communication:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm514678.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
Teva Pharmaceuticals Communication:
http://www.fda.gov/Safety/Recalls/ucm514656.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

GUIDE FOR TENNCARE PHARMACIES: OVERRIDE CODES

OVERRIDE TYPE	OVERRIDE NCPDP FIELD	CODE
Emergency 3-Day Supply of Non-PDL Product	Prior Authorization Type Code (D.0 461-EU)	8
Hospice Patient (Exempt from Co-pay)	Patient Residence (D.0 384-4X)	11
Pregnant Patient (Exempt from Co-pay)	Pregnancy Indicator (D.0 335-2C)	2
Titration Dose Override for the following select drugs/drug classes: oral oncology agents, anticonvulsants, warfarin, low molecular weight heparins, theophylline, Selective Serotonin Reuptake Inhibitors (SSRIs), Selective Norepinephrine Reuptake Inhibitors (SNRIs), atypical antipsychotics (except clozapine/Clozaril®), Hizentra®, Vivaglobin® - process second Rx for the same drug within 21 days of initial Rx with an override code to avoid the second Rx counting as another prescription against the limit.	Submission Clarification Code (D.0 42Ø-DK)	2
Titration Dose Override for the following select drugs/drug classes: clozapine/Clozaril®, Suboxone®, Zubsolv® and buprenorphine- will allow up to five prescription fills to process for the same drug within a month of the initial prescription without the subsequent fills counting against the enrollee's monthly RX limit.	Submission Clarification Code (D.0 42Ø-DK)	6

Important Phone Numbers:

TennCare Family Assistance Service Center	866-311-4287
TennCare Fraud and Abuse Hotline	800-433-3982
TennCare Pharmacy Program Fax	888-298-4130
Magellan Pharmacy Support Center	866-434-5520
Magellan Clinical Call Center	866-434-5524
Magellan Call Center Fax	866-434-5523

Helpful TennCare Internet Links:

Magellan: https://tenncare.magellanhealth.com
TennCare website: www.tn.gov/tenncare/

Please visit the Magellan TennCare website regularly to stay up-to-date on changes to the pharmacy program. For additional information or updated payer specifications, please visit the Magellan website at: https://tenncare.magellanhealth.com then click on pharmacy and choose program information from the drop down menu. Please forward or copy the information in this notice to all providers who may be affected by these processing changes.

Thank you for your valued participation in the TennCare program.