Sagent – Recall of phenylephrine injection

- On March 11, 2021, Sagent announced a voluntary, user-level recall of three lots of phenylephrine injection as the result of a customer complaint due to potentially loose crimped vial overseals. A non-integral crimped vial overseal may result in a non-sterile product.

  — Clinical Services, through the Drug Safety Notification program, did not identify any members that may be affected by this recall. Mailings will not be conducted.
  — Other lots of phenylephrine injection are available for patients to use.

- The lot numbers being recalled were distributed to hospitals, wholesalers and distributors nationwide in the U.S. from 11/17/2020 - 3/08/2021.

Product Description	NDC#	Lot# (Expiration Date)
Phenylephrine hydrochloride injection	25021-315-01	PHT8IB2 (8/2022), PHT9IB2 (8/2022), PHT1JB2 (9/2022)

- Phenylephrine injection is an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important low blood pressure resulting primarily from the dilation of blood vessels, which decreases blood pressure in the setting of anesthesia.

- Intravenous administration of a product intended to be sterile that is not sterile could result in serious systemic infections which may be life-threatening. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated.

- To date, Sagent has not received reports of any adverse events associated with this issue.

- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled phenylephrine injection.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.

- Contact Sagent at **1-866-625-1618** for more information about this recall.