The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you that the following lots; 4206, 4210, 4223, 24231, 24237, and 4196 of Venofer® (Iron Sucrose) Injection, USP as listed above are manufactured and distributed by American Regent, Inc. and are the subject of a Recall by the manufacturer. Recall of this product to USER LEVEL was initiated due to a potential for glass de-lamination of the vials.

Venofer ® (Iron Sucrose) Injection is indicated for the treatment of iron deficiency anemia (IDA) relative to chronic kidney disease (CKD) in the following patients:

- Adult Patients with Hemodialysis Dependent-Chronic Kidney Disease (HDD-CKD);
- Adult Patients with Non-Dialysis Dependent-Chronic Kidney Disease (NDD-CKD);
- Adult Patients with Peritoneal Dialysis Dependent-Chronic Kidney Disease (PDD-CKD);
- Pediatric Patients (2 Years of Age and Older) with HDD-CKD for Iron Maintenance Treatment;
- Pediatric Patients (2 Years of Age and Older) with NDD-CKD or PDD-CKD who are on Erythropoietin Therapy for Iron Maintenance Treatment.

Risk Assessment:

The aforementioned lots may contain microscopic glass particles that could potentially cause adverse health effects if injected, including vascular injury, embolism, thrombosis, or local reactions at the injection site due to the delamination of glass flakes from the vial's inner surface. Any particulate matter/residue, even if totally dissolved, are not expected to cause adverse effects systemically due to the relatively low volume of Venofer injected. In this particular instance, there was no obvious solubility of the flakes/particulates expected. Sub-particles that may have dissolved from the flakes/particles are not likely to exist, and even if present, are not expected to cause clinical concern.

Based on the Toxicological and Safety analysis, when Venofer is used according to the approved prescribing procedures, at this time there is low potential risk of any particulate matter entering the systemic circulation with consequent adverse reactions or causing an immunologic or immunogenic response at the injection site.

Product Information	**Product**: Venofer® (Iron Sucrose) Injection, USP **NDC No**.: 49230-530-01; 49230-530-10; 49230-530-25 **Strength:** 50mg/ 2.5mL (20mg/mL) **Package Size:** 10x2.5mL/ vial 25x2.5mL/ vial **Lot No:** 4206 **Expiration Date:** 2026-05 **Lot No:** 4210 **Expiration Date:** 2026-05 **Lot No:** 4223 **Expiration Date:** 2026-06 **Lot No:** 24231 **Expiration Date:** 2026-07 **Lot No:** 24237 **Expiration Date:** 2026-07
Product Information	**Product:** Venofer® (Iron Sucrose) Injection, USP **NDC No.:** 49230-534-01; 49230-534-25 **Strength**: 100mg/ 5mL (20mg/mL) Package Size: 25x5mL/ vial **Lot No:** 4196 **Expiration Date:** 2026-05