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.

Insulet is conducting a Medical Device Correction for specific lots of Omnipod® 5 Pods due to a manufacturing issue identified through our ongoing product monitoring. This action may affect some of your patients who use Omnipod® 5 Pods.

Insulet has identified that certain Pods from specific lots may have a small tear in the internal tubing that delivers insulin. If this occurs, insulin may leak inside the Pod instead of being fully infused in the body as intended.

This action applies only to specific Omnipod® 5 Pod lots distributed in the United States. Pods not included in these lots, as well as all other Omnipod® products, remain safe to use.

Customers should visit omnipod.com/check-pods to confirm whether their Pod lot number is included in this Medical Device Correction. There may be multiple Pods from the same affected lot within a single box. Customers should not use any Pods with the listed lot numbers.

The Pods involved in this correction represent approximately 1.5% of annual Omnipod® 5 Pod production globally.
If insulin is not delivered properly, users may experience high blood glucose levels due to under-delivery of insulin. In the most severe cases, prolonged and persistent high blood glucose levels can lead to diabetic ketoacidosis (DKA), a serious medical condition that requires prompt medical treatment and can be life-threatening if not treated.

Insulet has received 18 reports of serious adverse events associated with high blood glucose levels, including hospitalization and diabetic ketoacidosis. No deaths have been reported.

This issue does not affect continuous glucose monitoring (CGM) systems or CGM readings.