Background Information: On June 4, 2020, AvKARE issued a consumer-level recall of Metformin Hydrochloride Extended-Release 500 mg tablets and 750 mg tablets manufactured by Amneal that were repackaged and distributed by AvKARE. **AvKARE issued this recall because it was notified that Metformin Hydrochloride Extended-Release tablets, USP, 500 mg and 750 mg, showed N-nitrosodimethylamine (NDMA) amounts above acceptable levels, and because Amneal is issuing a voluntary recall of all non-expired lots in conjunction with the FDA out of abundance of caution.**

This may represent a potential health hazard or safety risk to plan members who may be using product affected by this recall.

A complete list of the affected products and lot numbers affected by this recall is can be found in the attachments.

NDMA is classified as a probable human carcinogen based on laboratory tests. NDMA is a known environmental contaminant and is found in water and foods, including meats, dairy products, and vegetables. Metformin is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. Patients taking Metformin Hydrochloride Extended-Release 500 mg tablets and 750 mg tablets are advised by the United States Food and Drug Administration (FDA) to continue taking their medication and contact their health care professional who can prescribe a replacement. According to the FDA it could be dangerous for patients with type 2 diabetes to stop taking their Metformin without first talking to their health care professionals. The FDA has advised that patients should continue taking Metformin tablets even after recalls occur, until they consult with their health care professional who can prescribe a replacement.