



# NATIONAL ASSOCIATION OF MEDICAID FRAUD CONTROL UNITS

## **\$10 MILLION JOINT SETTLEMENT WITH ROYAL PHARMACEUTICALS AND SETON PHARMACEUTICALS FOR UNDERPAYMENT OF MEDICAID REBATE DRUGS**

The National Association of Medicaid Fraud Control Units (NAMFCU) announced on December 15, 2020 that 49 states and the District of Columbia joined a \$10,397,052 nationwide settlement with Royal Pharmaceuticals LLC and Seton Pharmaceuticals LLC (Royal/Seton). The settlement was reached after the two jointly-held pharmaceutical companies self-disclosed a pricing error that resulted in the underpayment of Medicaid drug rebates to the states from 2013 to 2017.

In July 2018, Royal/Seton self-reported an error in the companies' Medicaid Drug Rebate Program (MDRP) data to the North Carolina Medicaid Fraud Control Unit. As part of the MDRP, drug manufacturers are required to pay rebates to state Medicaid programs for each of the company's drugs that are covered by Medicaid. From September 2013 to January 2017, Royal/Seton inadvertently yet inaccurately reported the "Market Date" data element that is part of the Centers for Medicare and Medicaid Services' (CMS) calculation of each drug's rebate amount. The drugs at issue were two low-potency topical steroid products: "Derma-Smoothe," which is made by Royal and its generic equivalent "fluocinolone," made by Seton. This error caused CMS's rebate calculation to result in a lower calculated rebate amount, and consequently, Royal/Seton's rebate underpayments.

A NAMFCU Team participated in the settlement negotiations on behalf of the states. The Team included representatives of the Offices of the Attorneys General for the states of California, Florida, North Carolina, and Texas and the Illinois State Police, Medicaid Fraud Control Bureau.