



Dear Manufacturers:

I am writing on behalf of St. Mary's Hospital & Medical Center, Inc. ("St. Mary's"; SCH060023-00) to inform manufacturers that St. Mary's underwent an audit by the Health Resources and Services Administration ("HRSA") of St. Mary's compliance with 340B Drug Pricing Program ("340B Program") requirements. The audit occurred in 2013.

By way of background, St. Mary's is located in Grand Junction, Colorado. At the time of the HRSA audit, St. Mary's qualified for the 340B Program as a Sole Community Hospital ("SCH"). St. Mary's participated in the 340B Program as a SCH from November 1, 2011 until September 30, 2014.

Through the audit process, HRSA found St. Mary's to have non-compliance within its 340B Program and is responsible for repayment as a result of the following findings:

St. Mary's dispensed 340B drugs to ineligible individuals and does not have adequate controls to prevent diversion, as prohibited by 42 USC 256b(a)(5)(8). HRSA identified six dispensations from St. Mary's contract pharmacies that were filled for patients who were seen by physicians who were not on St. Mary's medical staff. St. Mary's worked with its contract pharmacy software vendor, MacroHelix, to implement more stringent protocols to ensure that 340B drugs are only provided to eligible patients who are under the care and responsibility of St. Mary's.

St. Mary's does not have adequate controls to prevent duplicate discounts as prohibited by 42 USC 256b(a)(S)(A). Upon further review, St. Mary's, working with HRSA and the applicable State Medicaid agency, discovered only one instance since St. Mary's participation in the 340B Program where a Medicaid patient received a 340B priced drug. This was due to the patient becoming retroactively eligible for traditional Medicaid.

St. Mary's has identified all affected manufacturers by expanding the scope of HRSA's audit sample to include all dispensations back to St. Mary's original participation date in the 340B Program (11/1/2011). St. Mary's is contacting each affected manufacturer to notify them of these violations and to begin a dialogue on a method of repayment to affected manufacturers. If manufacturers have not received notification from St. Mary's and believe repayment may be owed for the violations described in this letter, or if you have any questions or comments regarding the violations described in this letter, please contact Bryon Donovan, Category Manager – Pharmacy, at (303) 813-5446, or SCL Health System, 2420 W. 26th Avenue, Suite D-100, Denver, CO 80211.

We appreciate the opportunity to collaborate with HRSA and manufacturers in order to uphold the integrity of the 340B Program.