



MINISTRY HEALTH CARE

Dear Manufacturers,

I am writing on behalf of St. Elizabeth Hospital (340B ID # DSH520009) (“St. Elizabeth”) to inform manufacturers that St. Elizabeth recently underwent an audit by the Health Resources and Services Administration (HRSA) of St. Elizabeth’s compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, St. Elizabeth qualified for the 340B Program as a disproportionate share hospital in Appleton, Wisconsin and has participated in the 340B Program since April 1, 2012.

Through the audit process, St. Elizabeth was found to have non-compliance within their 340B Program and may be responsible for repayment as a result of the following finding(s):

1. “St. Elizabeth dispensed 340B drugs to ineligible individuals, as prohibited by section 340B(a)(5)(B) of the PHSA.”

This issue stemmed from two prescriptions which were improperly deemed 340B-eligible. One prescription was for a patient who received treatment from a provider outside of 340B covered entity space, and another was for a patient who was an inpatient at the time of prescription. In order to address these incidents, St. Elizabeth has significantly narrowed the prescription eligibility window in addition to ensuring that its eligible patient listing is sourced accurately. The change was implemented as of May 5, 2016 and St. Elizabeth will conduct follow-up audits consistent with the corrective action plan approved by HRSA to help ensure that 340B drugs are not dispensed to ineligible individuals.

2. “St. Elizabeth does not have adequate controls to prevent duplicate discounts which may have resulted in duplicate discounts as prohibited by section 340B(a)(5)(A) of the PHSA”

At the time of the audit, St. Elizabeth used drugs purchased at 340B pricing for Medicaid patients at one child site (St. Elizabeth’s Midway Surgery Center- DSH 520009A), despite indicating that such child site would not bill Medicaid for drugs purchased at the 340B price. St. Elizabeth, however, did not bill Medicaid for such drugs. Further, as of July 5, 2016, St. Elizabeth implemented a system which identifies all Medicaid patients receiving services at the Midway Surgery Center and ensures that any drugs provided to those patients are purchased using a Wholesale Acquisition Cost (WAC) and not 340B account. In the spirit of good faith compliance, this has been implemented without regard to



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whether or not drugs are bundled for purposes of the Medicaid program in order to simplify the analysis of compliance with the 340B Program's duplicate discount standard.

St. Elizabeth has identified all affected manufacturers and will contact each to notify them of these violations to begin a dialogue on a method for repayment to affected manufacturers. If manufacturers have not received notification from St. Elizabeth 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 Bryan Pearce, System Director - 340B Drug Discount Program at (715) 479-0312 or bryan.pearce@ministryhealth.org.