

Dear Manufacturers,

I am writing on behalf of Spectrum Health Hospitals (SHH; 340B ID DSH230038) to inform manufacturers that SHH recently underwent an audit by the Health Resources and Services Administration (HRSA) of SHH's compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, SHH qualified for the 340B Program as a disproportionate share hospital in Grand Rapids, Michigan and has participated in the 340B Program since April 1, 2004.

Through the audit process, SHH 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. "SHH dispensed 340B drugs to ineligible individuals, as prohibited by section 340B(a)(5)(B) of the PHSA."**

In order to address this issue, which was related to a subset of patients treated by prescribers related to SHH outside of SHH 340B covered entity space, SHH has narrowed significantly its prescription eligibility window to reduce the potential for processing ineligible claims. The change was implemented as of April 1, 2016 and SHH 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. "SHH listed incorrect or incomplete information on the 340B Medicaid Exclusion File."**

At the time of the audit SHH had listed an incorrect NPI in the 340B Medicaid Exclusion File for three child sites (DSH230039AE, AF and AH). That error has been corrected. Although Spectrum incorrectly listed its NPI number in the Medicaid Exclusion File for these three child sites, only one 340B-eligible claim was dispensed from these sites. This dispense was not billed to the payor and was held until the Medicaid Exclusion File was updated. More, since all SHH claims submitted to Michigan Medicaid included the parent site NPI that was and remains correctly listed in the 340B Medicaid Exclusion File, we do not believe any duplicate discounts could have occurred had a claim been submitted. As such, SHH does not intend to directly notify any manufacturers of this issue.

SHH has identified all affected manufacturers and will contact each within thirty days of this letter 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 SHH 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 Ryan Foster, Senior Director of Pharmacy at 616-391-3028 or [Ryan.Foster@spectrumhealth.org](mailto:Ryan.Foster@spectrumhealth.org).