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Dear Manufacturers,

I am writing on behalf of St. Joseph Health System (SJHS: 340B ID SCH230100-00) to inform manufacturers that in September of 2015, SJHS underwent an audit by the Health Resources and Services Administration (HRSA) of SJHS compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, SJHS qualified for the 340B Program as a Sole Community Hospital (SCH) providing services within Iosco County, MI and has participated in the 340B Program since July of 2012.

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

SJHS listed incorrect information on the 340B Medicaid Exclusion File, which is used to prevent duplicate discounts as prohibited by section 340B(a)(5)(A) of the PHSA.

Specifically, SJHS failed to remove a site-specific NPI (#1689662421) from the 340B Medicaid Exclusion File after Great Lakes Practice Clinic child site (340B ID SCH230100-03) (Clinic) operations ceased. The Clinic last submitted a claim for payment on March 11, 2014 and was completely closed effective May 1<sup>st</sup> of 2014. SJHS requested that the Clinic be removed from the OPA database as a child site on May 1<sup>st</sup> of 2014 and that termination was effective October 1, 2014.

The State of Michigan Medicaid Office confirmed that no claims were processed since the closure of this clinic and that the last claim processed by Medicaid for the NPI was in March of 2014, prior to the closure of the clinic and removal from the 340B program. The NPI at issue was removed from the Medicaid Exclusion file on or before January 14, 2016, though again not claims were submitted under this NPI after March 11, 2014 which prior to the Clinics cessation of 340B Program participation.

Based on the information noted above which has been confirmed by the Michigan Medicaid Office, SJHS believes that no duplicate discounts could have occurred and that the Michigan Medicaid Office had all information necessary to appropriately exclude or process manufacturer rebates. As such, since we are unable to identify that any manufacturers were subject to duplicate discounts, we do not intend to contact any manufacturers directly.

If manufacturers have not received notification from SJHS and believe repayment may be owed for the findings described in this letter, or if you have any questions or comments regarding the findings described in this letter please contact:



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