

Dear Manufacturers,

I am writing on behalf of Children's Hospital Medical Center of Akron, PED363303-00, to inform manufacturers that Children's Hospital Medical Center of Akron recently underwent an audit by the Health Resources and Services Administration (HRSA) of Children's Hospital Medical Center of Akron's compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, Children's Hospital Medical Center of Akron qualified for the 340B Program as a children's hospital located in Akron, Ohio and has participated in the 340B Program since February of 2010.

Through the audit process, Children's Hospital Medical Center of Akron was found to have non-compliance within their 340B Program and responsible for repayment as a result of the following finding(s):

- Dispensed 340B drugs to ineligible individuals, as prohibited by section 340B of the PHSA
- 340B drugs were not properly accumulated. ACH did not have adequate controls in place to ensure proper accumulation and prevention of diversion of 340B drugs, as prohibited by section 340B (a)(5)(B) of the PHSA.
- ACH listed incorrect or incomplete information on the 340B Medicaid Exclusion File. This action may have resulted in duplicate discounts as prohibited by section 340B(a)(5)(B) of the PHSA.

We have evaluated and corrected the above findings. We determined that a small number of manufacturers were affected.

Children's Hospital Medical Center of Akron has identified all affected manufacturers and has contacted 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 Children's Hospital Medical Center of Akron 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 John E. Lepto, R.Ph., Director of Pharmacy Services, 330-543-8320. One Perkins Square, Akron, Ohio, 44308.

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