

November 02, 2015

Dear Manufacturers,

I am writing on behalf of Henry Ford Hospital (HFH; 340B ID DSH230053) to inform manufacturers that Henry Ford Hospital recently underwent an audit on August 20-21, 2013, by the Health Resources and Services Administration (HRSA) of Henry Ford Hospital's compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, Henry Ford Hospital qualified for the 340B Program and is designated as a Disproportionate Share hospital (DSH230053) located at 2799 West Grand Blvd, Detroit, MI 48202 and has participated in the 340B Program since October 1, 2002.

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

HFH used a replenishment model that potentially included replenishing a covered outpatient drug from one manufacturer with a covered outpatient drug sold by a different manufacturer. HFH did not have adequate controls in place to ensure proper accumulation and prevention of diversion of 340B drugs, as prohibited by 42 USC 256b(a)(5)(B). However, during this audit HRSA did not find any evidence that supported diversions.

Henry Ford Hospital's 340B purchases are predominately outpatient only locations. HFH reviewed its purchase invoices for mix-use and inpatient accounts for the period of January 1, 2011 to November 8, 2013 to validate that 11 digit NDC replenishment for generic drugs occurred in a consistent manner, where there is a WAC purchase (after August 7, 2013) or GPO (prior to August 7, 2013) prior to 340B purchase. This review did not identify 11-digit NDC diversion occurred.

Henry Ford Hospital does not believe any manufacturers were affected by inappropriate 11-digit NDC replenishment. It should be noted that in November 2013, Henry Ford Hospital implemented a process to capture of the exact drug NDC that is administered to patients in its replenishment software.

Henry Ford Hospital believes no repayment is required since diversion did not occur. If manufacturers 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

Sincerely,

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Edward G. Szandzik  
Vice President, Inpatient Pharmacy  
Services  
Henry Ford Health System

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Edward Chadwick  
Executive Vice President & Chief Financial  
Officer  
Henry Ford Health System