

April 13, 2015

Dear Manufacturers,

I am writing on behalf of the University of Kentucky (UK) (DSH180067) to inform manufacturers that UK recently underwent an audit by the Health Resources and Services Administration (HRSA) of UK's compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, UK qualified for the 340B Program as a Disproportionate Share Hospital in Lexington, KY and has participated in the 340B Program since December 1, 1992.

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

**Finding 1: UK dispensed 340B drugs to ineligible individuals, as prohibited by 42 USC 256b(a)(5)(B).**

**Covered entities are prohibited by 42 USC 256b(a)(5)(B) from reselling or otherwise transferring a 340B drug to a person who is not a patient of the entity. Patient eligibility requirements are defined in guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996)). The sample revealed that UK's contract pharmacies deemed 11 prescriptions 340B-eligible even though they should not have been eligible. One of the prescriptions was dispensed from Kroger pharmacy and there was no medical record to support the episode of care which resulted in the prescription. Ten of the prescriptions were dispensed from PCA Corrections and originated from an ineligible site that was not listed as reimbursable as an outpatient service on UK's Medicare cost report (MCR). All costs and revenues associated with these visits are charged to Subprovider - Inpatient Psychiatric Facility on the MCR. All 340B drugs dispensed or prescriptions deemed 340B-eligible which originated from PCA Corrections are considered diverted which is prohibited under 42 USC 256b(a)(5)(B). These instances do not meet the patient definition guidelines and therefore constitutes diversion as prohibited by 42 USC 256b(a)(5)(B).**

UK 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 UK 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:

UK HealthCare  
Office of Corporate Compliance  
859-323-9817  
2333 Alumni Park Plaza, Suite 330  
Lexington KY 40517

Sincerely,

Ann Smith, MPA, FACHE  
Chief Administrative Officer  
UK HealthCare, Hospitals