

July 10, 2015

Dear Manufacturers,

I am writing on behalf of Transylvania Regional Hospital, 340B ID# CAH341319-00 to inform manufacturers that Transylvania Regional Hospital recently underwent an audit by the Health Resources and Services Administration (HRSA) of our compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, Transylvania Regional Hospital qualified for the 340B Program as a Critical Access Hospital located at 260 Hospital Drive, Brevard NC and has participated in the 340B program since 8/11/2010.

Through the audit process Transylvania Regional Hospital was found to have non-compliance within their 340B Program and is responsible for repayment as a result of the following findings:

1. For the period 10/1/2013 to 4/1/2014 Transylvania was purchasing orphan drugs through the 340B Drug Pricing Program contrary to its listings in the 340B database, creating the need for repayment to 12 manufacturers.
2. Contrary to patient definition guidelines, 340B drugs were administered to a patient after that patient had been admitted as an inpatient.

Transylvania Regional Hospital is in the process of notifying affected manufacturers 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 Transylvania Regional Hospital and believe repayment may be owed for the violations described in this letter, or if you have questions or comments regarding the violations described in this letter please contact Alan Knudsen, Pharmacy Specialist, 340B Program, 428 Biltmore Avenue, Room W232, Asheville NC 28801, phone number 828-213-4213.

Marc Nakagawa
Regional Finance Director
Transylvania Regional Hospital