

October 2, 2015

Dear Manufacturers,

I am writing on behalf of the Dallas County Hospital District (DCHD), dba Parkland Health & Hospital System (TX) (DSH450015) to inform manufacturers that DCHD recently underwent an audit by the Health Resources and Services Administration (HRSA) of DCHD's compliance with the 340B Drug Pricing Program (340B Program) requirements.

As background, DCHD qualified for the 340B Program as a Disproportionate Share Hospital in Dallas, Texas and has participated in the 340B Program since December 1, 1992.

Through the audit process, DCHD was found to be non-compliant within their 340B Program and responsible for repayment as a result of the following finding:

DCHD 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 audit revealed that 10 of the 28 sampled 340B drugs were incorrectly deemed 340B eligible by its contract pharmacies. The prescriptions were written by ineligible providers at ineligible facilities (physician private practices not reimbursable on DCHD's Medicare Cost report) for DCHD employees, and DCHD did not maintain medical records to support that responsibility of the care provided remained with DCHD. These instances do not meet the patient definition guidelines and therefore constitutes diversion as prohibited by 42 USC 256b(a)(5)(B).

DCHD has identified all affected manufacturers and will notify them of this violation and begin a dialogue. If manufacturers have not received notification from DCHD or have any questions or comments regarding the violation described in this letter please contact:

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dba Parkland Health & Hospital System
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Sincerely,

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