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Dear Manufacturers:

I am writing on behalf of Lawrence General Hospital (LGH) (DSH220010) to inform manufacturers that LGH recently underwent an audit by the Health Resources and Services Administration (HRSA) of LGH's compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, LGH qualified for the 340B Program as a Disproportionate Share Hospital in Lawrence, Massachusetts and has participated in the 340B Program since July 1, 2004.

Through the audit process, LGH was found to have non-compliance within their 340B Program and is responsible for repayment as a result of the following finding: *LGH does not have adequate controls to prevent diversion and dispensed 340B drugs to ineligible individuals, as prohibited by 42 USC 256b (a) (5) (B).*

- a. LGH's response to the finding of a single dispensation occurrence of "no drug order or doctor's note could be found to support 340B-eligibility" included: (1) identification of a single clerical computer keystroke error resulting in an errant manual charge of a medication (2) removal of that medication dispensation from outpatient replenishment and reallocation to inpatient replenishment, and (3) provision of repayment to the manufacturer through a reduction in 340B replenishment and purchase of one complete box of medication on the LGH non-GPO/WAC account to ensure that the manufacturer was properly compensated beyond the dose dispensation documented during the HRSA audit.
- b. LGH's response to the finding of "four drugs given to individuals in observation (outpatient status) which were later determined to be inpatient" included: (1) identification of an inadvertent delay of the Admit, Discharge & Transfer (ADT) message from outpatient to inpatient status due to a small period of erratic interface communications with the third party, split-billing vendor, Sentry Data Systems (2) an intense assessment, repair, cleansing, and testing of the interface and split-billing database at the hospital and vendor level (3) identification of each affected medication at the 11-digit NDC level and corresponding manufacturer (4) removal of each identified medication dispensation from outpatient replenishment and reallocation to inpatient replenishment, and (5) provision of repayment to the manufacturers through a reduction in 340B replenishment and purchase of one complete box of each medication at the 11-digit NDC level on the LGH non-GPO/WAC account to ensure that the manufacturers were properly compensated beyond the dose dispensations documented during the HRSA audit.

LGH 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 LGH 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 Deborah J. Wilson, Chief Financial Officer, 978-683-4000, 1 General Street, Lawrence, Massachusetts 01841.