

DATE: November 18, 2014

FROM: Ms. Debra A. Muscio
Chief Audit, Ethics and Compliance Officer
Community Medical Center
789 N Medical Center Drive East
Clovis, CA 93611
Community Regional Medical Center
2823 Fresno Street
Fresno, California 93721

TO: Manufacturer

Re: 340B Program Audit for Community Regional Medical Center (DSH050060)

Dear Manufacturers,

I am writing on behalf of Community Regional Medical Center (CRMC) to inform manufacturers that CRMC (DSH050060) recently underwent an audit by the Health Resources and Services Administration (HRSA) of CRMC's compliance with 340B Drug Pricing Program (340B Program) requirements.

BACKGROUND

As background, CRMC (which is located in Fresno, CA) qualified for the 340B Program as a DSH Hospital and has participated in the 340B Program since April 1, 2007.

Through the audit process, the following findings were identified:

1. CRMC had an inaccurate database record, and
2. CRMC lacked sufficient internal controls to prevent diversion within its Ambulatory Pharmacy due to a configuration issue within the split-billing software system.

Both of the above matters were voluntarily disclosed to HRSA at the time of audit, as these matters had been previously identified through a compliance audit conducted by an independent audit firm that was engaged by the Chief Audit, Ethics and Compliance Officer. Additionally, CRMC took immediate corrective actions to resolve both matters prior to the HRSA audit. Subsequent to HRSA's audit, CRMC through its Audit and Compliance Department, conducted a follow-on audit of the Ambulatory Pharmacy operations to evaluate the effectiveness of the 340B controls. No subsequent findings were observed.

CORRECTIVE ACTION TAKEN ON FINDINGS

Finding #1 - the inaccurate database entry was removed from CRMC's 340b registration record at the first possible opportunity after the audit.

Finding #2 - the software configuration was immediately corrected and CRMC implemented multiple internal controls to mitigate the risk of diversion. These controls included hiring a full time 340B

Program Manager and enhancing system-wide monitoring and auditing procedures. CRMC is also in the final stages of upgrading its 340B split-billing software that will provide enhanced compliance monitoring.

All of these actions have been taken as part of a HRSA -approved corrective action plan.

NOTIFICATION TO MANUFACTURERS

As part of the HRSA audit process, CRMC is required to submit a response to notify manufacturers to the extent diversion occurred. At the completion of the HRSA audit, CRMC conducted a series of comprehensive analyses that included an internal analysis followed by an additional external analysis performed by an independent audit firm. Both audits found no evidence of diversion within the Ambulatory Pharmacy. Although CRMC acknowledges internal control gaps existed, we have found no evidence that would necessitate repayment. Regarding finding one, the analysis showed that although a facility was registered incorrectly on the OPA database, the facility did not have the ability to purchase or dispense 340B medications and no evidence of diversion was detected. Regarding finding 2, the analysis showed no evidence of ineligible transactions replenishing on the 340B account and no evidence of diversion. The analysis may be provided upon request.

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CRMC strives to create a culture that promotes understanding and adherence to applicable federal, state, and local regulations and laws. If manufacturers believe repayment may be owed for the findings described in this letter, or if you have any questions or comments regarding the findings described in this letter please contact: Debra A. Muscio, Chief Audit, Ethics and Compliance Officer, 559-324-4830, 789 N Medical Center Drive East, Clovis CA 93611.

Sincerely,

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cc: Tim A. Joslin, President and CEO, Community Medical Centers
Craig A. Wagoner, CEO of Community Regional Medical Center
Joseph M. Nowicki, CFO of Community Regional Medical Center

