

Revised: March 7, 2017
Original: November 10, 2016

Dear Manufacture:

I am writing on behalf of Family Medical Center of Michigan, Inc. 340B ID# CH052910 to inform manufacturers that Family Medical Center of Michigan, Inc. recently underwent an audit by the Health Resources and Services Administration (HRSA) of Family Medical Center of Michigan, Inc. compliance with 340B Drug Pricing Program (340B Program) requirements.

As background, Family Medical Center of Michigan, Inc. qualified for the 340B Program as a Federally Qualified Health Center and located at 8765 Lewis Avenue, Temperance, Michigan 48182 and has participated in the 340B Program since October 1, 2001.

Through the audit process, Family Medical Center of Michigan, Inc. was found to have noncompliance within their 340B Program and responsible for repayment as a result of the following finding(s):

Diversion:

Finding 1: FMCM dispensed 340B drugs to ineligible individuals, as prohibited by section 340B (a) (5) (B) of the PHSA.

Covered entities are prohibited by section 340B (a) (5) (B) of the PHSA from reselling or otherwise transferring of 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)). FMCM's contract pharmacies (Walgreens #2023 located at 1285 N. Monroe Street, Monroe, MI; and Walgreens #5321 located at 484 South Telegraph Road, Monroe, MI) incorrectly deemed two samples prescriptions 340B-eligible. The prescriptions were written by provider at ineligible sites (providers' private offices which were not authorized through FMCM's grant). FMCCM had no referral arrangement or patient records to support the responsibility for care, resulting in the prescriptions, remained with FMCM. All sites that purchased and used 340B Drugs for their eligible patients must be listed on the 340B database. In order for non-hospital health care delivery sites to purchase 340B drugs or provide 340B drugs to their patients, they must first be authorized through the (non-hospital) covered entity's grant and list on the 340B database.

These instances do not meet the patient definition guidelines and therefore constitute diversion as prohibited by 340B (a) (5) (B) of the PHSA.

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Family Medical Center of Michigan, Inc. has identified all affected manufacturers and has contacted each to notify them of the violation to begin a dialogue on a method for repayment to affected manufacturers. If manufacturers have not received notification from Family Medical Center of Michigan, Inc. 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 Chris Croley, CFO, 734-850-6915, or FMC 8765 Lewis Ave., Temperance, MI 48182.

Thank you.

Ed Larkins,
Chief Executive Director

Cc: Chris Croley