



ESTABLISHING MATERIAL BREACH THRESHOLD 340B PROGRAM COMPLIANCE

Bullhook Community Health Center defines a material breach of compliance as a violation(s) that exceeds 5 percent of audit samples, exceeds \$2500, or impacts any one organization more than 5 percent. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that [meet or] exceed this threshold, and that remain non-correctable within 3 months of review, will be immediately reported to HRSA (at 340Bselfdisclosure@hrsa.gov) and applicable manufacturers using the following self-disclosure report template:

https://docs.340bpvp.com/documents/public/resourcecenter/ALL_Entities_Self_Reporting_340B_Non_Compliance.docx Bullhook Community Health Center has compliancy officers that oversee this process, reviews potential violations, performs materiality assessment, and determines if a material breach has occurred. The compliancy officers identifies to whom to self-disclose the breach dependent on that materiality determination and the corrective action plan resolution. On behalf of Bullhook Community Health Center the pharmacy director reviews this policy annually, makes decisions about the material breach definition and self-disclosure and submits any changes to the Board for approval. Bullhook Community Health Center maintains records (including all internal or external correspondence and corrective action plans) of violations, materiality assessment, and resolution of manufacturer self-disclosure and/or formal self-disclosure to HRSA.

Any employee that feels there has been a material breach should contact any one of the following positions:

1. Compliancy Officer 1: CEO
2. Compliancy Officer: Billing Lead Supervisor
3. Pharmacy Director

Any employee reporting a material breach shall not be retaliated against as a report of this material breach and is protected under Bullhook Community Health Center’s policy regarding retaliation. Any breaches found will be submitted as above to HRSA in addition a corrective action plan will be submitted by department coordinator or manager of department involved in material breach within 10 days of HRSA self-disclosure forms being filled out. In addition, compliancy officers will review at 3 months from time of incident to ensure all necessary action items complete.



CHIEF EXECUTIVE OFFICER

Date: 6-27-18



CHAIR, BOARD OF DIRECTOR

Date: 6/27/18

Date first adopted	06/12/2018
Date Revised/QI Board approval	06-05-2018
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