

RECEIVED  
SEP 11 2018



Setting the Standard in Health Care Excellence

### Response to Grand Jury Report Form

Report Title: Ventura County Medical Center 340B Drug Pricing Program

Report Date: April 26, 2018

Response by: Johnson Gil  
Kim Milstien

Title: Director, Health Care Agency  
Title: Chief Executive Officer, Ventura County Medical Center

#### FINDINGS / CONCLUSIONS

I (we) agree with the Findings / Conclusions numbered: FA-06, FA-08, FA-10, C-01, C-02, C-03, C-04, C-05

I (we) disagree wholly or partially with the Findings / Conclusions numbered: FA-01, FA-02, FA-03, FA-04, FA-05, FA-07, FA-09.

(Attach a statement specifying any portions of the Findings / Conclusions that are disputed; include an explanation of the reasons.)

#### RECOMMENDATIONS

Recommendations numbered R-04 has been implemented.  
(Attach a summary describing the implemented actions and date completed.)

Recommendations numbered R-01, R-03 have not yet been implemented, but will be implemented in the future.  
(Attach a time frame for the implementation.)

Recommendations numbered R-02, R-05 require further analysis.

Recommendations numbered will not be implemented because they are not warranted or are not reasonable.

Date: June 29, 2018 Signed: Johnson Gil

Date: June 29, 2018 Signed: [Signature]

Number of pages attached: 5



Setting the Standard in Health Care Excellence

June 29, 2018

The Honorable Patricia M. Murphy  
Presiding Judge, Superior Court of California  
County of Ventura  
800 S. Victoria Avenue  
Ventura, CA 93009

Mr. Andrew Ludlum  
Foreperson, 2017-2018 Ventura County Grand Jury  
800 S. Victoria Avenue  
Ventura, CA 93009

**SUBJECT: VENTURA COUNTY HEALTH CARE AGENCY AND VENTURA COUNTY MEDICAL CENTER RESPONSE TO 2017-2018 VENTURA COUNTY CIVIL GRAND JURY FINAL REPORT DATED APRIL 26, 2018: VENTURA COUNTY MEDICAL CENTER 340B DRUG PRICING PROGRAM**

Dear Judge Murphy and Mr. Ludlum:

Please find enclosed in the requested format Ventura County Health Care Agency and Ventura County Medical Center's Response to the 2017-2018 Ventura County Civil Grand Jury's April 26, 2018 Final Report: Ventura County Medical Center 340B Drug Pricing Program.

If you have any questions or require additional information, please contact Johnson Gill at (805) 677-5272 or Kim Milstien at (805) 652-6058. We appreciate the opportunity to respond to this report.

Respectfully submitted,

Handwritten signature of Johnson Gill in blue ink.

Johnson Gill  
Health Care Agency Director  
Ventura County Health Care Agency

Handwritten signature of Kim Milstien in blue ink.

Kim Milstien  
Chief Executive Officer  
Ventura County Medical Center

Enclosure

Johnson K. Gill  
Health Care Agency Director  
VCMC Administrator

Matthew Sandoval  
Chief Deputy Director  
Compliance Officer

Joan R. Araujo, RN, MHA  
Chief Deputy Director  
Hospital Replacement Wing

Tara Diller  
Animal Services Director

Sevet Johnson, PsyD  
Behavioral Health Director

Kim S. Milstien  
Deputy Director  
VCMC / SPH Chief Executive Officer

Dee Pupa  
Deputy Director  
Managed Care / Patient Accounting  
Health Care Plan Administrator

Rigoberto Vargas, MPH  
Public Health Director

Christopher R. Young, MD  
Chief Medical Examiner

**Response to Grand Jury Report Form**

Report Title: Ventura County Medical Center 340B Drug Pricing Program

Report Date: April 26, 2018

Response by: Johnson Gil Title: Director, Health Care Agency  
Kim Milstien Title: Chief Executive Officer, Ventura County Medical Center

Response Date: June 29, 2018

**FACTS**

**FA-01.** VCMC was audited by HRSA in 2015. The results of the audit revealed VCMC was in violation of the 340B program in five major areas, including receiving duplicate discounts on 340B program medications. After the HRSA audit, VCMC was required to pay back money to pharmaceutical companies and placed on probation by the OPA. (Ref-01)

**Response: Partially Disagree.** Health Resources and Services Administration (HRSA)'s audit of Ventura County Medical Center (VCMC)'s 340B Drug Pricing Program resulted in five total findings affecting four major areas: Group Purchasing Organization (GPO) Prohibition, Incorrect 340B Database Record, Diversion of 340B Medications and Duplicate Discounts. VCMC received discounts on medications in the form of 340B discounts, but VCMC did not receive two discounts for the same medication. Affected drug manufacturers may have issued duplicate discounts for 340B medications, one to VCMC in the form of a 340B discount, and another to Medi-Cal in the form of a Medicaid rebate. VCMC has worked with affected drug manufacturers in determining the final amount of repayment owed, and has provided repayment to these affected drug manufacturers.

**FA-02.** There are approximately 500 hospitals in the state of California in the 340B program, 95% of those hospitals are in compliance. (Ref-02)

**Response: Disagree.** 340B Health (Ref-02 <https://www.340bhealth.org/files/CA.pdf>) lists 181 hospitals in the State of California that participate in the 340B program. In 2015, HRSA conducted 340B compliance audits of 117 Disproportionate Share Hospital covered entities across the nation (Ref-01 <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-15-audit-results.html>) which resulted in the following:

- 86.3% (101/117) had audit findings.
- 67.5% (79/117) were required to provide repayment to affected drug manufacturers.
- 9.4 % (11/117) were required to terminate part or all of their 340B program.
- 13.7% (16/117) had no adverse findings.

**FA-03.** VCMC implemented a corrective action plan in July 2015. VCMC is using the same in-house personnel to monitor and audit the 340B program after the HRSA audit. (ATT-02)

**Response:** Partially Disagree. VCMC agrees that a corrective action plan was implemented after the HRSA July 2015 audit. However, VCMC added a Pharmacy Supervisor position to oversee pharmacy operations in 2015. This position ensures there are controls in place in Pharmacy Supply Chain and Charge Services to reduce the risk of 340B non-compliance.

**FA-04.** VCMC uses an outside contractor, Verity Solutions, for billing of 340B drugs. While it was hired in 2012, Verity Solutions was not fully functional until 2015. During this time period, VCMC was also using a GPO for billing.

**Response:** Disagree. VCMC does not use Verity Solutions or a GPO for billing of 340B drugs. Verity Solutions, formerly known as Talyst, provides a split-billing software subscription that ensures that VCMC purchases medications in accordance to 340B program regulations. This program ensures that VCMC is billed on the appropriate drug wholesaler account (GPO, 340B or Wholesale Acquisition Cost (WAC)) when purchasing drugs to replenish its inventory. VCMC has had a contract with Verity Solutions, formerly known as Talyst, for this software subscription since 2007.

**FA-05.** The simultaneous use of two billing entities resulted in VCMC claiming duplicate discounts. Duplicate discounts occur when companies sell drugs at a discount under the 340B program to VCMC and then VCMC also claims Medicaid rebates on the same drugs. (Ref-01)

**Response:** Disagree. VCMC listed incorrect or incomplete billing information on the 340B Medicaid Exclusion File, which may have resulted in duplicate discounts. The affected drug manufacturers may have issued a duplicate discount for 340B medications, one to VCMC in the form of a 340B discount, and another to Medi-Cal in the form of a Medicaid rebate.

**FA-06.** VCMC has completed negotiations with 23 pharmaceutical companies. The original amount owed these companies was \$2.1 million. As a result of the negotiations, VCMC was able to reduce their repayment to \$861,000. VCMC is still in negotiation with two other pharmaceutical companies over a potential repayment of \$428,000. (Att-01)

**Response:** Agree. This information was accurate at the time the Ventura County Grand Jury requested this information. As of June 29, 2018, VCMC has completed final review and negotiations with 25 affected drug manufacturers. The original amount owed to these 25 affected drug manufacturers was \$2,633,732.02. Through further analysis and negotiations, this repayment amount was reduced to \$1,162,705.60. There is one analyses in process with an affected manufacturer, with a potential total repayment of \$14,555.65. 51 affected drug manufacturers have been unresponsive or have become unresponsive to VCMC's request to close all matters relating to its July 2015 HRSA 340B Drug Pricing Program audit.

**FA-07.** Nineteen pharmaceutical companies forgave the duplicate discounting and are not requiring repayment of \$361,000. (Att-01)

**Response: Partially Disagree.** Affected drug manufacturers have forgiven VCMC for any repayment amount owed as a result of findings identified in the 2015 HRSA 340B audit. As of June 29, 2018, twenty affected drug manufacturers have forgiven VCMC for any repayment owed, for a total of \$362,723.07.

**FA-08.** There are 53 pharmaceutical companies who have been unresponsive to date. The potential amount owed is \$976,000. (Att-01)

**Response: Agree.** This information was accurate at the time the Ventura County Grand Jury requested this information. As of June 29, 2018, a total of 51 affected drug manufacturers have not been responsive or have become unresponsive to VCMC's request to close all matters relating to its July 2015 HRSA 340B Drug Pricing Program audit. The potential amount owed to these affected drug manufacturers totals \$849,678.86.

**FA-09.** VCMC had no controls in place to ensure proper accumulation and to avoid improper diversion of 340B drugs.

**Response: Partially Disagree.** VCMC did have some controls in places such as separate purchasing accounts for GPO, 340B and WAC purchases, as well as a separate physical inventory for 340B qualified clinics. However, the HRSA audit did reveal that these controls were insufficient to ensure proper accumulations and to avoid improper diversion of 340B drugs.

**FA-10.** With increased Congressional interest, the federal government is likely to scrutinize the 340B program, calling for more audits and justification on how the program money is spent.

**Response: Agree.** VCMC agrees that there is increased Congressional interest in the 340B program with current legislation calling for greater transparency in how the 340B program is administered and utilized. These include bills include Senate Bill 2312-Helping Ensure Low-Income Patients have Access to Care and Treatment (HELP) Act and House Bill 4710-The 340B Protecting Access for Underserved and Safety-Net Entities Act (PAUSE).

## **CONCLUSIONS**

**C-01.** The Grand Jury concluded there was not proper oversight of the VCMC 340B program prior to the 2015 HRSA audit. This has resulted in VCMC reimbursing pharmaceutical companies at least \$861,000 and potentially as much as \$1.6 million. (FA-01, FA-02, FA-03, FA-06, FA-07, FA-08)

**Response: Agree.** VCMC agrees that there was not proper oversight of the VCMC 340B program with respect to tracking the purchasing and billing of medications prior to the 2015 HRSA audit. The reimbursement figures are accurate based on data provided to the Grand Jury during its investigation. As of June 29, 2018, VCMC has completed its analyses and negotiations with affected drug manufacturers and has reimbursed or will be reimbursing affected drug manufacturers a total of \$1,162,705.60.



**C-02.** The Grand Jury concluded that before the 2015 HRSA audit, there were few controls in place in the 340B program and no checks to see if VCMC was in compliance with HRSA. (FA-01, FA-02)

**Response:** Agree. Although VCMC had some controls in place for the 340B program such as separate purchasing accounts for GPO, 340B and WAC purchases, and a separate physical inventory for 340B qualified clinics, the 2015 HRSA audit proved these controls to be insufficient to track the purchasing and billing of medications according to 340B program rules.

**C-03.** The Grand Jury concluded that the extensive corrective action plan created for the VCMC 340B program after the 2015 HRSA audit appears to have adequate safeguards to prevent duplicate discounting in the future. (FA-04, FA-05)

**Response:** Agree. In addition to the corrective action plan, VCMC has added logic into its billing software system that will automatically add a 340B identifier called a “UD modifier” to 340B medications, minimizing the risk of duplicate discounts.

**C-04.** The Grand Jury concluded while VCMC conducts its own in-house audits of the 340B program, more critical audits should be conducted by an independent outside party. (FA-03, FA-09)

**Response:** Agree. VCMC agrees that more critical audits should be conducted by an independent outside party to ensure VCMC is in full compliance with 340B Drug Pricing Program regulations and to identify any vulnerabilities so that they can be immediately corrected.

**C-05.** The Grand Jury concluded the federal government is likely to demand VCMC track its use of 340B money and program savings. (FA-10)

**Response:** Agree. This assumes Senate Bill 2312-Helping Ensure Low-Income Patients have Access to Care and Treatment (HELP) Act or House Bill 4710-The 340B Protecting Access for Underserved and Safety-Net Entities Act (PAUSE) passes and is signed into law.

## RECOMMENDATIONS

**R-01.** The Grand Jury recommends VCMC consider bringing in outside resources with extensive 340B program experience to assist in the supervision of the corrective action plan. (C-01, C-02, C-03)

**Response:** Will be implemented. VCMC is currently in the process of engaging with an outside resource with extensive 340B program experience to validate the corrective action plan. This will be implemented in the next 90 days.

**R-02.** The Grand Jury recommends VCMC request the Ventura County Auditor-Controller conduct regular compliance audits of the 340B program (C-03, C-04)

**Response:** Requires further analysis. VCMC will work with the engaged outside resource identified in R-01 and discuss how best to set up regular compliance audits of the 340B program based on national best practices.

**R-03.** The Grand Jury recommends VCMC continue in-house audits and share all results and recommendations with employees and the public. (C-03, C-04)

**Response:** Will be implemented. VCMC will share results of in-house audits with the Compliance Committee of the Ventura County Health Care Agency (VCHCA) and VCMC's Oversight Committee on a regular basis. Additionally, HRSA Office of Pharmacy Affairs (OPA) has outlined a process for self-disclosure of any findings determined to be a material breach. This self-disclosure process will be followed when any material breach is discovered.

**R-04.** The Grand Jury recommends VCMC study the management, personnel, and operational changes necessary to ensure the violation-free operation of the 340B program. (C-01, C-02)

**Response:** Has been implemented. VCMC has reviewed its management, personnel and operations and added a Pharmacy Supervisor position to oversee Pharmacy Operations in 2015. This position ensures there are controls in place in Pharmacy Supply Chain and Charge Services to ensure 340B compliance. Additionally, the Huron Consulting Group has recommended adding a 340B Program Manager position to the Pharmacy Department to ensure there are committed resources to oversee the 340B program at VCMC. VCMC leadership is in the process of evaluating this recommendation.

**R-05.** The Grand Jury recommends that VCMC establish a system to track how the money from the 340B program is used, as this is likely to be a subject of future Congressional interest.

**Response:** Requires Further Analysis. VCMC will work with the engaged outside resource identified in R-01 and discuss how other 340B covered entities establish a system, if any, to track how the money from the 340B program is used. This system should reflect national best practices.