



RECEIVED

Apr 12 2019

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

Sirote & Permutt, PC
2311 Highland Avenue South
Birmingham, AL 35205-2972
PO Box 55727
Birmingham, AL 35255-5727

Lenora W. Pate
Attorney at Law
lpate@sirote.com
Tel: 205-930-5162
Fax: 205-212-3801

April 12, 2019

VIA E-MAIL (shpda.online@shpda.alabama.gov)

Emily T. Marsal
Executive Director
State Health Planning & Development Agency
100 North Union Street, Suite 870
Montgomery, Alabama 36104

**Re: Project No. AL2016-006; CON 2745-H
University of South Alabama Medical Center
Project Modification Request**

Dear Ms. Marsal:

Pursuant to the Alabama Certificate of Need ("CON") Program Rules and Regulations ("CON Rules"), including 410-1-10-.03, the University of South Alabama Medical Center ("USAMC") respectfully submits this project modification request (the "Request") and describes herein the unforeseen costs related to the operation of the relocated USAMC Fairhope Outpatient Department in its new leased space in a new medical office building resulting in this Request (the "Project").

As discussed in the USAMC Final Progress Report of April 12, 2019, following the USAMC Fairhope Outpatient Department's first year of operations, the total first year operating costs for all three (3) divisions of the USAMC Fairhope Outpatient Department, including the Outpatient Infusion Therapy, Clinical Laboratory, and Pharmacy divisions, is **\$7,684,620.88**. This first year operating cost is higher than the estimated total first year operating cost of **\$4,826,963.00** reported in the USAMC Fairhope Outpatient Department CON Application.

Additionally, the increase in the first year operating cost of the USAMC Fairhope Outpatient Department resulted in an increase in the total cost of the Project of greater than 10%, as illustrated in the table on the following page.

Birmingham Huntsville Mobile Tuscaloosa Fort Lauderdale Orlando



Emily T. Marsal
April 12, 2019
Page 2

	CON Application	Actual Cost
Facility Lease Cost Per Year	$\$131,387.80 \times 15 \text{ years} =$ $\$1,970,817.00$	$\$76,752.00 \times 15 \text{ years} =$ $\$1,151,280.00$
Equipment Cost	$\$22,310.90 \times 7 \text{ years} =$ $\$156,176.30$	$\$63,315.78^1$
First Year Annual Operating Cost	\$4,826,963.00	\$7,684,620.88
Total Cost	\$6,953,956.30	\$8,899,216.66

Considering that the actual first year operating costs resulted in an increase in the total cost of the Project in excess of 10%, USAMC herein submits this Request to update the Project to incorporate the actual costs of the USAMC Fairhope Outpatient Department. In support of the Request, USAMC sets forth the following information related to the circumstances which led to first year operating costs higher than those estimated and reported in the USAMC Fairhope Outpatient Department CON Application:

- (a) **Services volumes** for the year 2015 were used in estimating the first year annual operating costs in the USAMC Fairhope Outpatient Department relocation CON Application. The **actual services volumes** for the relocated USAMC Fairhope Outpatient Department Infusion Therapy division in 2018 were **23.02% higher** than such volumes in 2015;
- (b) Despite being a participant in the federal 340B Drug Pricing Program,² drug costs in connection with the USAMC Fairhope Outpatient Department operations **increased** over the three (3) year period from the filing of the USAMC Fairhope Outpatient Department CON Application until the first year of operations for each of the divisions of the USAMC Fairhope Outpatient Department;³ and

¹ Note that while the USAMC CON Application indicated that USAMC would lease equipment, USAMC ultimately realized savings by **purchasing** the equipment.

² Pursuant to section 340B of the Public Health Service Act ("PHSA"), the Department of Health and Human Services ("HHS") enters pharmaceutical pricing agreements with certain drug manufacturers, which agree that the prices they charge for certain covered outpatient drugs to certain covered entities will not exceed 340B ceiling prices, as defined by statute. See HRSA, *Defining Scope of Project and Policy for Requesting Changes*, Policy Information Notice ("PIN") 2008-01 at 3 (Dec. 31, 2007).

³ While 340B Drug Pricing Program providers must meet rigorous requirements in order to ensure that vulnerable patients are given increased access to affordable drugs and services, providers have noted that **"the government has failed to hold manufacturers to the same standard" and have voiced concerns regarding the prices charged by pharmaceutical manufacturers**. American Hospital Association, *Hospital Groups File Lawsuit to Shine Needed Light on Drug Company*



Emily T. Marsal
April 12, 2019
Page 3

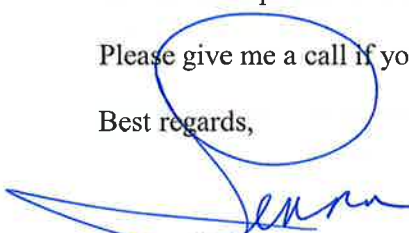
- (c) In addition, physician utilization of drugs has changed. Physicians practicing at the USAMC Fairhope Outpatient Department have utilized drugs which were more beneficial but were more expensive than those used at the time costs, including drug costs, were estimated for the first year operating costs in the USAMC Fairhope Outpatient Department CON Application in 2015.

Considering that there was no opposition to this Project and there are no parties of record in underlying administrative proceedings concerning this Project, no parties are required to be notified regarding this Request.

In accordance with CON Rule 410-1-3-.09, a text searchable pdf copy of this Request is being submitted electronically on April 12, 2019, to shpda.online@alabama.gov, and a paper original of this filing will be preserved in our files. Also, a check in the amount of \$7,607.60, 35% of the original CON Application fee, is being sent on April 12, 2019, by separate letter via Federal Express for delivery to SHPDA on April 15, 2019, for the fee required for this Project Modification Request.

Please give me a call if you have any questions.

Best regards,



Lenora W. Pate
Jordan Jackson
FOR THE FIRM
LWP/jj

Pricing and Overcharging, <https://www.aha.org/press-releases/2018-09-11-hospital-groups-file-lawsuit-shine-needed-light-drug-company-pricing-and> (Sept. 11, 2018).

HHS has recently issued a final rule which implements drug price ceilings and civil monetary penalties for manufacturers under the 340B Drug Pricing Program beginning in 2019. 83 Fed. Reg. 61563 (Nov. 30, 2018). HHS first proposed the rule in June 2015 and finalized its requirements in January 2017; however, HHS ultimately delayed the rule's effective date in order to develop "new comprehensive policies to address the rising costs of prescription drugs," including drug pricing in programs such as 340B. *Id.* at 61564.

Due to HHS's delay of the rule's effective date, the American Hospital Association ("AHA"), along with the Association of American Medical Colleges and America's Essential Hospitals, brought suit against HHS, arguing that the delay harmed hospitals. AHA, *Hospital Groups File Lawsuit to Stop Significant Payment Cuts for 340B Hospitals*, <https://www.aha.org/press-releases/2017-11-13-hospital-groups-file-lawsuit-stop-significant-payment-cuts-340b-hospitals> (Nov. 13, 2017). HHS ultimately moved the effective date of the final rule from July 1, 2019 to January 1, 2019. **The AHA stated, "[T]oday's final rule ensures implementation of the long-delayed 340B Drug Pricing Program ceiling price and civil monetary penalties polices will be effective January 1, 2019. Earlier this year, the AHA along with other national organizations representing 340B hospitals, filed a lawsuit to force implementation of this rule in order to shine needed light on drug pricing and to hold price-gouging drug companies accountable."** AHA, *Statement on Final 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Rule*, <https://www.aha.org/press-releases/2018-11-29-statement-final-340b-drug-pricing-program-ceiling-price-and-civil> (Nov. 29, 2018).

Birmingham Huntsville Mobile Tuscaloosa Fort Lauderdale Orlando



Emily T. Marsal
April 12, 2019
Page 4

c: Karen McGuire
Deborah Compton
Jean W. Tucker, Esq.
Melissa Long, Esq.