

Quality and Productivity Commission
33rd Annual Productivity and Quality Awards Program
"Empowering Innovative Solutions"

2019 APPLICATION

Title of Project (Limited to 50 characters, including spaces, using Arial 12 point font):

NAME OF PROJECT: 340B DRUG BILLING SOFTWARE

DATE OF IMPLEMENTATION/ADOPTION: 10/24/2017

(MUST HAVE BEEN FULLY IMPLEMENTED FOR A MINIMUM OF AT LEAST ONE YEAR - ON OR BEFORE JULY 1, 2018)

PROJECT STATUS: Ongoing One-time only

HAS YOUR DEPARTMENT PREVIOUSLY SUBMITTED THIS PROJECT? Yes No

EXECUTIVE SUMMARY: Describe the project in 15 lines or less using Arial 12 point font. State clearly and concisely what difference the project has made.

1 Olive View Medical Center, as part of LA County Department of Health Services (LA DHS),
 2 is a covered entity of the federal 340B Drug Program and provides discounted drugs to
 3 eligible outpatients. Health Resources & Services Administration (HRSA), overseeing the
 4 program, upholds participants with strict requirements to control diversion of discounted
 5 drugs and audits covered entities periodically. Ensuring compliance can be a challenge
 6 for a hospital that services both outpatient and inpatients as well as maintaining accurate
 7 documentation. To overcome the challenges, DHS started a program with OVMC as the
 8 first phase. We implemented and utilized split billing software (Verity®) to create electronic
 9 record of all drug transactions received from DHS electronic health record, ORCHID. The
 10 electronic management provided accurate transaction data which enabled increased
 11 utilization of 340B drugs from 51% to 58% of total cost, gain improved knowledge of
 12 overall drug utilization/readiness for itemized billing and has liberated pharmacy from
 13 maintaining physical separation of 340B and non-340B drugs. Successful implementation
 14 of this program paves the way for all qualified DHS entities to achieve further operational
 15 efficiencies, enabling our mission to provide care to the most vulnerable patients.

BENEFITS TO THE COUNTY

(1) ACTUAL/ESTIMATED ANNUAL COST AVOIDANCE	(2) ACTUAL/ESTIMATED ANNUAL COST SAVINGS	(3) ACTUAL/ESTIMATED ANNUAL REVENUE	(1) + (2) + (3) = TOTAL ANNUAL ACTUAL/ESTIMATED BENEFIT	SERVICE ENHANCEMENT PROJECT
\$ 55,888,280.75	\$ NOT APPLICABLE	\$ Not Applicable	\$ 55,888,280.75	

ANNUAL = 12 MONTHS ONLY

SUBMITTING DEPARTMENT NAME AND COMPLETE ADDRESS

OVMC Pharmacy
 14445 Olive View Dr, Rm 1C101
 Sylmar, CA 91342-1495

TELEPHONE NUMBER
 747-210-3059

PROGRAM MANAGER'S NAME

Nadrine Balady-Bouziane
 Julianne Joo
 Paula Seloadji

TELEPHONE NUMBER
 747-210-3059

EMAIL
 nbalady@dhs.lacounty.gov

PRODUCTIVITY MANAGER'S NAME AND SIGNATURE
(PLEASE CALL (213) 893-0322 IF YOU DO NOT KNOW YOUR PRODUCTIVITY MANAGER'S NAME)

Connie Salgado-Sanchez

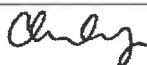


DATE
 06/27/19

TELEPHONE NUMBER
 213-288-8483

EMAIL
 cosanchez@dhs.lacounty.gov

DEPARTMENT HEAD'S NAME AND SIGNATURE
 Christina R. Ghaly, M.D.



DATE
 6/27/19

TELEPHONE NUMBER
 213-288-8050

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Background

The 340B Program was created by Congress in 1992 to help vulnerable or uninsured patients gain access to medication by requiring pharmaceutical company to provide steep discounts to eligible clinics and hospitals for covered outpatient drugs. The program is intended *“to stretch scarce Federal resources as possible, reaching more eligible patients and providing more comprehensive services.”* Olive View Medical Center has been a covered entity of 340B program since 1998 as it meets eligibility criteria as a disproportionate share hospital (DSH).

Challenges

The challenge of the 340B program comes in efforts to ensure compliance with program requirements to prevent diversion of discounted drugs, while managing the real life issues that arise in drug distribution. The covered entity is required at minimum to 1) keep accurate and up-to-date information of its program eligibility to recertify annually 2) avoid duplicate discounts (340B and Medicaid drug rebate) and 3) dispense only to those that meet eligible patient definition.

The program defines an eligible patient as a covered entity's patient who receives outpatient services including drugs prescribed by the covered entity's own prescriber. This becomes a challenge for an entity that services both outpatients and inpatients such as Olive view because of what is known as *GPO Prohibition*. GPO (group purchasing organization) prohibition states that in order to participate in the 340B program, the covered entity may not obtain covered outpatient drugs through a GPO or other group purchasing agreement. This creates a big undertaking for pharmacy, as it needs to maintain three separate physical inventories containing 340B, GPO and WAC (wholesale acquisition cost) drugs. 340B drugs can be used only for eligible outpatients, GPO only for inpatients and WAC for patients in mixed use areas where the patient status may change from outpatient to inpatient, such as in emergency department. Typically, 340B drugs are discounted 25-50% and GPO 15-20% compared to wholesale WAC price. Outpatient pharmacy providing outpatient prescriptions is excluded from this requirement as it purchases solely 340B drugs and services outpatient status patients.

To maintain three inventories with three matching drug list is physically limited by pharmacy's space and leads to significant waste, considering outpatient status patients require a common group of medications for dedicated outpatient related services while inpatients require group of medications more reserved and necessary for hospital level of care. When a drug is not available in one inventory, it was considered unavailable to the patient even though it may be available in another. The 340B program also restricts borrow and transfer with a non-340B account, unless it is used for emergent situations. There were also attempts to meet compliance by providing a dedicated automated dispensing cabinet (Pyxis®) in the patient unit.

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For example, emergency department had a dedicated Pyxis® machine which provided GPO purchased drugs and nursing was instructed to use it when the patient status changed from outpatient to inpatient. However, rules were not intuitive and at times restrictions went against patient care. The situation became worse in the event of a drug shortage where it was impossible to maintain three separate inventory or keep enough in one inventory.

Additionally, it was evident during OVMC audit by HRSA in 2015 that to show evidence of program compliance was of great challenge. In preparation of the audit, pharmacy worked to provide records from point of purchase up to dispensing to qualifying patient with understanding that an 11-digit NDC (national drug code) match must be shown. Although reports of drug purchases were easy to obtain, it was difficult to show that a 340B purchased drugs was dispensed to an eligible patient with full certainty because of lack of record of the drugs in its full path of transaction. At the time, pharmacy had fragmented records from one program to another (wholesaler drug purchase, medication inventory carousel and Affinity order records).

Solutions

On October 24, 2017, OVMC Inpatient Pharmacy implemented a 340B auto-split billing program, utilizing Verity Solutions software. This allows the pharmacy to convert from a physical inventory to a virtual replenishment model. This inventory model virtually tracks 340B eligible drugs that have been dispensed at the pharmacy and replenish 340B medications where appropriate. This project benefits pharmacy, nursing staff and patients. Resources from multiple departments are required for initial maintenance and to provide ongoing management of program requirements. The Information Technology uploads the transaction files. Pharmacy reviews dispenses and expenditures to minimize unnecessary WAC purchases. ORCHID Pharmacy performs formulary maintenance. Providers' orders and nursing administration documentation are critical so that each medication dispense is recorded. The main technology used is Verity Solutions that interfaces with the hospital's ADT (an admission, discharge, and transfer system) and electronic medical record.

Benefits

The benefit of this project is it assures 340B Program compliance against diversion and Medicaid duplicate discounts. The software interfaces with wholesaler record as well as current electronic health record (ORCHID) and allows full documentation of the utilization of all drugs. ADT data is used to ensure that patient status and location are consistent with the 340B Program patient definition and dispenses are from eligible providers. Payor source is identified to accurately reflect Medicaid patients to avoid Medicaid duplicate discounts. Improved documentation has strengthened OV's program and increased readiness for future HRSA audits.

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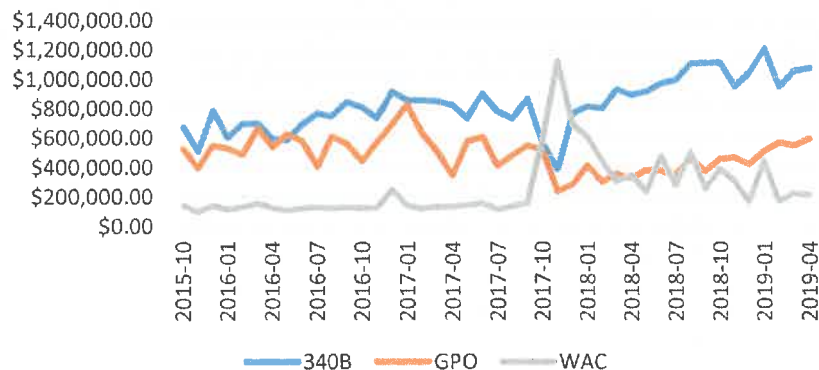
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Since its implementation in quarter 4 of 2017, we focused our assessment up to quarter 1 of 2019 excluding the quarter around the program inception. The observation post implementation in drug expenditure is an increased trend of 340B purchases from an average of 51% in 2016 to 58% in the past year. This is likely derived from accurate capture of patient outpatient status from mixed-use area and increased capture of observation status patients. Interestingly, GPO purchase has decreased, while WAC purchase has increased. Overall, this is likely closer to a correct reflection of type of patients that we serve and the need to utilize WAC to support replenishment while complying with regulations.

	340B	GPO	WAC
2016			
Qtr1	49%	41%	10%
Qtr2	47%	44%	9%
Qtr3	55%	36%	9%
Qtr4	53%	37%	11%
2017			
Qtr1	52%	40%	8%
Qtr2	56%	35%	10%
Qtr3	56%	34%	10%
Qtr4	33%	20%	47%
2018			
Qtr1	51%	21%	27%
Qtr2	56%	22%	22%
Qtr3	59%	22%	19%
Qtr4	59%	25%	16%
2019			
Qtr1	57%	29%	15%
Accounts included in software			

Sum of Purchase Dollars



Another significant benefit is that there is no longer a requirement of physical separation of inventories thus no requirement of patient separation. The software automates the process and virtually tracks dispenses and purchases under the appropriate accounts, allowing the concept of "virtual inventory" and mixing of drugs that were purchased under different account. This in turn allows a much wider selection of formulary drugs to patients that need them at the time of need. It simplifies pharmacy operations and helps to eliminate duplication of costly medications being kept on shelf and especially becomes of value during critical shortages where there are not enough supply to purchase in three accounts. Relief from physical separation also allows patients of different status to be co-mingled in a given unit or the entire hospital. OVMC has planned to increase observation status patients to decrease cost for those that clinically do not require a hospital admission. The utilization of the software has removed concern of 340B compliance out of this consideration which existed prior and was considered as a stumbling block prior to use of the software.

Lastly, as a beneficial byproduct of the project, it addresses shared problems and assists in itemized billing readiness as it enables to characterize pharmacy charge capture. Pharmacy is able to accurately track where medications are being used by specific NDC (national drug code).

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Linkage to the County Strategic Plan – 1 page only. Which County Strategic Plan goal(s) does this project address? Explain how. Use Arial 12 point font.

This project addresses the County Strategic Plan goal to “**realize tomorrow’s government today**” by 1) implementing technology initiatives that enhance service delivery and increase efficiency (Strategy III.2.3), 2) maximizing revenue (Strategy III.3.1), and 3) implement a workplace of the future (Strategy III.3.6).

By implementing the 340B billing program with Verity Solutions, it allows the pharmacy to work in a more efficient manner and provide improved medication delivery to patients. Front line pharmacy staff do not have to physically segregate nor look for signs where a drug was purchased from. Consequently, patients have access to all available products in the pharmacy, no matter the location or encounter type. This flexibility in drug distribution also assists in OV hospital specific initiatives such as increasing observation status patients.

This project most definitely works toward maximizing revenue. 340B program provides deep discounts for most drugs with cost benefits most pronounced with high cost agents such as oncology drugs that may be more than \$10K per dose. The goal is to maximize 340B purchased drugs and minimize unnecessary wholesale WAC purchases, while complying with the 340B Program requirements to maintain program eligibility. As previously mentioned, in addition to cost savings, pharmacy is better prepared for future itemized billing which is also future initiative to maximize revenue.

The project also provides workplace of the future as physical inventory are no longer separated on different shelves. Additional pharmacy space was gained within existing department space as a result of one consolidated virtual inventory. Pharmacy added additional workstations and lessened clutter to support essential pharmacy activities such as unit dose prepackaging, filling crash carts, preparing for expired drug returns and more ample space for pharmacist clinical patient monitoring.

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COST AVOIDANCE, COST SAVINGS, AND REVENUE GENERATED (ESTIMATED BENEFITS TO THE COUNTY): If you are claiming cost benefits, include a calculation on this page. Please indicate whether these benefits apply in total or on a per unit basis, e.g., per capita, per transaction, per case, etc. You must include an explanation of the County cost savings, cost avoidance or new revenue that matches the numbers in the box. Remember to keep your supporting documentation. Use Arial 12 point font

Cost Avoidance: Costs that are eliminated or not incurred as a result of program outcomes. Please indicate whether these are costs to the County or to other entities.

Cost Savings: A reduction or lessening of expenditures as a result of program outcomes. Please indicate whether these were expenditures by the County or by other entities.

Revenue: Increases in existing revenue streams or new revenue sources to the County as a result of program outcomes.

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Verity was implemented on October 24, 2017. We focused the assessment on the pre and post-implementation data, excluding the period around program inception. The cost benefit of the project is essentially the overall avoided drug cost. The calculated annual cost avoidance is \$55,888,280.75, which Olive View would have spent without 340B account. This is the amount purchased under the 340B and wholesale compared to GPO pricing. It is compared to GPO because without 340B Program, Olive View would need to purchase all drugs under this less discounted account. Below table explains the total annual cost avoidance in more detail.

Time Period	Account	Purchased Extended Sale	Comparison Extended Sale	Variance
May 2016 to April 2017	Outpatient Clinics	\$9,504,845.64	\$21,579,021.12	\$12,074,175.48
	Outpatient Pharmacy	\$4,665,718.85	\$30,864,396.02	\$26,198,677.17
	Outpatient Central Fill	\$1,360,164.22	\$14,796,308.28	\$13,436,144.06
	Wholesale (WAC)	\$1,615,995.60	\$1,444,592.17	-\$171,403.43
	TOTAL	\$17,146,724.31	\$68,684,317.59	\$51,537,593.28
May 2018 to April 2019	Outpatient Clinics	\$12,481,250.04	\$23,897,863.82	\$11,416,613.78
	Outpatient Pharmacy	\$7,725,173.76	\$38,601,701.08	\$30,876,527.32
	Outpatient Central Fill	\$1,741,032.05	\$15,879,266.03	\$14,138,233.98
	Wholesale (WAC)	\$3,651,394.64	\$3,103,793.65	-\$543,094.33
	TOTAL	\$25,598,850.49	\$81,482,624.58	\$55,888,280.75

The **Purchased Extended Sale** is the amount spent on the 340B and WAC accounts. The amount purchased in the 340B accounts include outpatient clinics, outpatient pharmacy, and outpatient central fill. The purchased amount is \$17,146,724.31 for May 2016 to April 2017 and \$25,598,850.49 for May 2018 to April 2019. The **Comparison Extended Sale** is the cost if everything was purchased under the GPO account. The Comparison Extended Sale is \$68,684,317.59 for May 2016 to April 2017 and \$81,482,624.58 for May 2018 to April 2019. The **Variance** is the difference between the Comparison Extended Sales and the Purchased Extended Sale. The Variance is the cost that is eliminated as a result of participating in the 340B Program (cost avoidance). The variance is \$51,537,593.28 for May 2016 to April 2017 and \$55,888,280.75 for May 2018 to April 2019.