



BOARD OF SUPERVISORS
AGENDA LETTER

Agenda Number:

Clerk of the Board of Supervisors
105 E. Anapamu Street, Suite 407
Santa Barbara, CA 93101
(805) 568-2240

Department Name: Public Health
Department No.: 041
For Agenda Of: July 7, 2015
Placement: Administrative
Estimated Tme:
Continued Item: No
If Yes, date from:
Vote Required: Majority

TO: Board of Supervisors

FROM: Department Takashi Wada, MD, MPH, Public Health Director
Director(s) Public Health Department
Contact Info: Dan Reid, Assistant Deputy Director, Public Health Department
681-5173

SUBJECT: **Pharmaceutical Agreements for the Public Health Department 340B Program and Bid Waiver Requests**

County Counsel Concurrence

As to form: Yes

Auditor-Controller Concurrence

As to form: Yes

Other Concurrence: Risk Management

As to form: Yes

Recommended Actions:

That the Board of Supervisors consider recommendations regarding a Professional Services Agreement:

- a) Approve and authorize the Chair to execute a Second Amendment to the Agreement with SUNRx, LLC Administrative Services, for the administration of the Public Health Department 340B Pharmacy Network for the period July 1, 2015 through June 30, 2018. This Agreement is expected to generate at least \$60,000 annually for the Public Health Department after administrative service costs.
- b) Approve and authorize the Chair to execute the CenCal Savings Share Agreement, to adjust and extend the existing partnership between CenCal Health and the Public Health Department for the Public Health Department's 340B Program for the period July 1, 2015 through June 30, 2018.
- c) Approve and authorize the Purchasing Manager to execute a Pharmaceutical Wholesaler Prime Vendor Agreement with AmerisourceBergen Drug Company, as approved to form and content by the Public Health Department Director, to provide pharmaceuticals for the Public Health Department pharmacies and for select 340B contract retail pharmacies in an amount not to exceed \$2,700,000 annually for a total maximum contract amount not to exceed \$8,100,000 for the period July 1, 2015 through June 30, 2018.

- d) Consider recommendations regarding Waivers of Competition under County Code 2-39 for the Purchase of pharmaceuticals, as follows:
 - i. Authorize the Purchasing Manager to procure pharmaceuticals for the 340B Program from Cardinal Health (not a local vendor) without requiring competitive bidding due to the contract pharmacies existing exclusivity relationships with Cardinal Health and to ensure 340B Program compliance for total purchase costs not to exceed \$2,500,000 per year and aggregate costs not to exceed \$7,500,000 for the period July 1, 2015 through June 30, 2018; and
 - ii) Authorize the Purchasing Manager to procure pharmaceuticals for the 340B Program from McKesson (not a local vendor) without requiring competitive bidding due to the contract pharmacies existing exclusivity relationships with McKesson and to ensure 340B Program compliance for total purchase costs not to exceed \$50,000 per year, and aggregate costs not to exceed \$150,000 for the period July 1, 2015 through June 30, 2018.
- e) Approve and authorize the Director of the Public Health Department to execute or terminate agreements with local 340B contract retail pharmacies to ensure sustainability of the program and access for patients throughout Santa Barbara County, without returning to the Board with a separate amendment, provided that any such revisions are within the scope of approved Purchasing authorizations, including applicable waivers of competition.
- f) Determine that these activities are exempt from California Environmental Quality Act review per CEQA Guideline Section 15378(b)(4), since the recommended actions are government fiscal activities which do not involve commitment to any specific project which may result in a potentially significant physical impact on the environment.

Summary Text:

This item is on the agenda to revise and continue the Public Health Department (PHD) 340B federal drug discount program and PHD's partnership with CenCal Health.

Recommended Action Items A and B are linked in that SUNRx provides assistance to the Public Health Department to manage 340B pharmaceutical claims and to determine which transactions are eligible for savings. Savings are generated as the difference between Medi-Cal reimbursements for pharmaceutical claims and actual 340B federal program discounts on these medications. The CenCal Health Savings Share Agreement is a partnership between the Public Health Department and CenCal Health to equally benefit from access to lower pharmaceutical costs for CenCal Health members. The Public Health Department uses these savings to support its programs of healthcare for the uninsured and underinsured clients in Santa Barbara County.

Recommended Action Item C is to authorize the Chair to approve a pharmaceutical wholesaler Agreement with the AmerisourceBergen Drug Company for the Public Health Department in-house pharmacies and several of the Public Health Department's 340B retail contract pharmacies. AmerisourceBergen Drug Company was awarded the bid in a competitive bid process for these pharmaceuticals in May 2015.

Recommended Action Item D is to authorize the County Purchasing Agent to issue two (2) new purchase orders (blanket purchase orders) agreements for McKesson and Cardinal Health

pharmaceutical wholesalers respectively without a competitive bid process. These agreements are necessary to serve the current Public Health Department’s 340B contract retail pharmacies; no other pharmaceutical wholesaler, including Cardinal Health and McKesson chose to participate in the public bid process for the Public Health Department’s in-house pharmacy pharmaceutical supply awarded to AmerisourceBergen Drug Company (see Recommendation C).

County Code Section 2-39 states that the Purchasing Agent is obligated to purchase all materials, supplies, furnishings and equipment using a formal competitive bidding process, unless the Board of Supervisors has waived competition under a particular set of circumstances. Due to the contract pharmacies existing exclusivity relationships with their pharmaceutical wholesaler (in these instances Cardinal Health or McKesson) and to ensure compliance with the 340B Program requirements, PHD is requesting your Board waive the requirement for a competitive bid for the purchase of certain pharmaceuticals for these two vendors. This bid waiver request is for FYs 2015-2016 through FY 2017-2018 in coordination with all other Agreements for the Public Health Department 340B Program.

Table 1 Estimates of annual pharmaceutical expenses for the PHD 340B program

Vendor	Product	Entities Served	Requested Amount
Recommendation C AmerisourceBergen Drug Company	Pharmaceuticals	PHD In-house pharmacies and 340B Contract Retail Pharmacies	\$8,100,000
Recommendation D Cardinal Health	Pharmaceuticals	340B Contract Retail and Specialty Pharmacies	\$7,500,000
Recommendation D McKesson	Pharmaceuticals	340B Contract Retail Pharmacies	\$150,000
Total			\$15,750,000

Recommended Action Item E will authorize the Public Health Department to make revisions or modifications to the number of facilities and pharmaceutical vendor representation of 340B contract retail pharmacies, should these changes be necessary to ensure access for PHD patients and geographic representation in the County of Santa Barbara.

Background:

SUNRx Administrative Services Agreement and CenCal Health Savings Share Agreements

On June 26, 2012, your Board authorized agreements with SUNRx and MedImpact (the pharmacy benefit manager contracted with CenCal Health to adjudicate pharmacy claims for CenCal Health members) to work with CenCal Health and PHD to establish the PHD 340B Contract Pharmacy Network (Pharmacy Network). With the establishment of the Pharmacy Network, PHD was able to purchase 340B discounted medications (through the federal 340B Drug Discount Program) to resupply those private pharmacies that are part of the Pharmacy Network and which fill PHD patient prescriptions at their pharmacy locations. Contracting with private pharmacies to participate in the Pharmacy Network has generated revenue for PHD and reduced CenCal Health’s pharmaceutical costs. For compliance with the 340B program requirements, PHD must ensure that the pharmaceuticals dispensed by the contract pharmacies as 340B program eligible prescriptions are replenished under the 340B program. The private pharmacies in the Pharmacy Network continue using their own pharmaceutical

wholesalers to replenish the pharmaceuticals supplied to PHD patients under this program. As such, PHD must contract with each of those wholesalers in order to ensure compliance with the 340B program and to replenish these pharmaceuticals.

All administrative costs for SUNRx and for the contracted retail pharmacies (dispensing fees) are calculated and subtracted from eligible Medi-Cal (CenCal Health) claims payments before determination of any 340B Program savings.

Over the last three years PHD has worked collaboratively with CenCal Health and SUNRx to administer the PHD 340B Program. The original intention of these Agreements was to achieve essential parity between reduced pharmaceutical expenses for the PHD in-house pharmacies and CenCal Health cost reductions experienced through the PHD 340B Program contracted retail and specialty pharmacies for 340B Program savings for CenCal Health members. Parity was not achieved in this initial Agreement and this new Agreement represents a change in the savings share split to move toward parity.

AmerisourceBergen Drug Company

The AmerisourceBergen Drug Company has provided wholesale pharmaceuticals for the PHD in-house pharmacies for many years and expanded this agreement in 2012 to include those 340B contracted retail pharmacies that have agreements with them for wholesale pharmaceuticals.

A small portion of the pharmaceuticals purchased are for federal programs such as the PHD Ryan White Part C program and include federal award funding. Due to the federal award requirements, a Request for Proposal (RFP) was published in April 2015. In May 2015, the PHD team and the County Purchasing Agent reviewed the only submittal (from the AmerisourceBergen Drug Company's) and deemed it satisfactory to the criteria outlined in the RFP.

The Agreement attached for AmerisourceBergen Drug Company includes participation in the Prime Vendor Program. In addition, PHD has negotiated with AmerisourceBergen Drug Company to include some of the County Board of Supervisors Standard Terms and Conditions.

Cardinal Health and McKesson

All Agreement costs are reimbursed from third party payers. Currently these are all paid through Medi-Cal (CenCal Health). As a necessary component for the implementation of the Pharmacy Network, bid waivers are requested for the following two (2) vendors for the purchase of pharmaceuticals. This is necessary as these pharmaceutical wholesalers resupply retail and specialty pharmacies in the current PHD 340B network. These two pharmaceutical wholesalers have been supplying the PHD contract pharmacies for many years and under Agreement with PHD since 2012.

Cardinal Health is a wholesaler for retail and specialty pharmacies participating in the Pharmacy Network. This bid waiver request will authorize the Purchasing Manager to issue a new purchase orders for up to \$2,500,000 each year, for a total aggregate not to exceed \$7,500,000 for pharmaceuticals associated with the Pharmacy Network during FYs 2015-2016, 2016-2017 and 2017-2018.

McKesson is a wholesaler for pharmacies participating in the Pharmacy Network. This bid waiver request will authorize the Purchasing Manager to issue a new purchase orders for up to \$50,000 each year, for a total aggregate not to exceed \$150,000 for pharmaceuticals associated with the Pharmacy Network during FYs 2015-2016, 2016-2017 and 2017-2018.

Mandates

The State of California mandates that the County provide access to necessary medical care under Section 17000 of the Welfare and Institutions Code. PHD is mandated to provide access to medical care under Sections 330 (e) and 330 (h) of the Public Health Service Act which also establishes its Federally Qualified Health Center status. These pharmaceuticals are necessary in order for PHD to deliver the necessary medical care. The 340B Program allows PHD to acquire these pharmaceuticals at discounted rates.

Performance Measure: The performance measures for these agreements are focused on replenishment and supply of pharmaceuticals in a timely manner and reliable supplies. The Public Health Department, as the party eligible for participation in the federal 340B drug discount program, is known as the covered entity and is responsible for ensuring compliance with all 340B requirements throughout its pharmacy network. As such, the SUNRx Administrative Services Agreement contains performance measures to assist PHD in maintaining compliance with these requirements. **Fiscal and Facilities Impacts:**

Budgeted: Yes **Fiscal Analysis:**

<u>Funding Sources</u>	<u>Current FY Cost:</u>	<u>Annualized On-going Cost:</u>	<u>Total One-Time Project Cost</u>
General Fund			
State		\$ 3,675,000.00	
Federal		\$ 1,575,000.00	
Fees			
Total	\$ -	\$ 5,250,000.00	0

The costs shown above are the total costs for all PHD pharmacy operations which includes both 340B and Non-340B operations and all in-house and contracted retail and specialty pharmacies. Revenue to offset these costs is from multiple sources such as Medi-Cal (CenCal Health), federal awards, Medicare, private insurance (very few patients) and self-pay patients that do not qualify for any healthcare coverage.

This action will allow for the Public Health Department to continue purchasing replenishment pharmaceuticals for its PHD 340B Contract Pharmacy Network. PHD will be reimbursed from CenCal Health for these pharmaceutical purchases through our existing agreement as a Medi-Cal provider for its members and through this revised Savings Share Agreement. This action adjusts the current Savings Share Agreement to ensure parity for the partnership between PHD and CenCal Health. These costs have been included in the PHD FY 15-16 adopted budget.

This action will not result in the need for any additional facilities.

There are no staffing impacts as a result of this action.

Key Contract Risks:

The Public Health Department has worked with all entities in these Agreements for the last three years and for many a much longer period of time. AmerisourceBergen Drug Company, McKesson and Cardinal Health are the three largest pharmaceutical wholesalers in the nation and are all financially stable. Although combined these represent multi-million dollar agreements within Santa Barbara County, this is less than 0.01% of these organizations' combined pharmaceutical business nationwide.

By having agreements with the three largest pharmaceutical wholesalers, should any one or possibly two of the wholesalers experience service or supply issues, the remaining agreements could be easily expanded to make up these shortfalls.

The greatest risk to the Public Health Department is to remain compliant with the federal 340B drug discount program. The County, as the covered entity eligible to participate in the program, bears all liability for ensuring compliance. These compliance issues are mitigated, to an extent, by inclusion of elements of oversight by SUNRx for PHD contracted retail and specialty pharmacies, ongoing regular meetings with SUNRx and CenCal Health to review program compliance and a robust monitoring and auditing internal and external program. PHD has been recognized for comprehensive compliance programs and its Pharmacy Director has provided presentations on the PHD compliance program at national 340B conferences.

PHD has also increased its 340B Program staff through the budget process and is developing additional capacity, separate from these agreements, to monitor 340B claims and audit contracted retail and specialty pharmacies at least annually.

Staffing Impacts:

Legal Positions:

N/A

FTEs:

N/A

Special Instructions:

Please execute two (2) originals of the SUNRx 340B Administrative Services 2nd Amendment and the CenCal Health 340B Savings Share Agreement and retain one (1) original Agreement for each of them and one (1) Minute Order for pick-up by the department. Please email phdcu@sbcphd.org when available for pickup.

Attachments:

- SUNRx 340B Administrative Services Agreement
- 1st Amendment to SUNRx 340B Administrative Services Agreement
- 2nd Amendment to SUNRx 340B Administrative Services Agreement
- CenCal Health and PHD 340B Savings Share Agreement
- AmerisourceBergen Drug Company Pharmaceutical Wholesaler Agreement

Authored by: Dan Reid, Assistant Deputy Director, 805-681-5173