

**AMENDMENT TO AGREEMENT
BETWEEN THE COUNTY OF SAN MATEO AND
S/T HEALTH GROUP CONSULTING, INC.**

THIS AMENDMENT TO THE AGREEMENT, entered into this ____ day of _____, 2016, by and between the COUNTY OF SAN MATEO, hereinafter called "County," and S/T Health Group Consulting, Inc., hereinafter called "Contractor";

W I T N E S S E T H:

WHEREAS, pursuant to Government Code, Section 31000, County may contract with independent contractors for the furnishing of such services to or for County or any Department thereof; and

WHEREAS, the parties entered into an Agreement for consulting and audit services on January 12, 2015; and

WHEREAS, the parties wish to amend the Agreement to add additional services to include quantitative review of pharmacy chargemaster and monthly NDC monitoring, increasing the amount by \$350,000 to a maximum amount not to exceed \$450,000.

NOW, THEREFORE, IT IS HEREBY AGREED BY THE PARTIES HERETO AS FOLLOWS:

1. Section 3, Payments, of the agreement is amended to read as follows:
 3. Payments. In consideration of the services rendered in accordance with all terms, conditions, and specifications set forth herein and any Exhibit(s) or attachment(s) attached hereto, County shall make payment to Contractor in the manner specified herein and in Exhibit A. In the event that the County makes any advance payments, Contractor agrees to refund any amounts in excess of the amount owed by the County at the time of contract termination. County reserves the right to withhold payment if County determines that the quantity or quality of the work performed is unacceptable. In no event shall total payment for services under this Agreement exceed FOUR HUNDRED FIFTY THOUSAND DOLLARS, (\$450,000).
2. Original Exhibit A is hereby replaced in its entirety with Revised Exhibit A (rev. 1/12/16), a copy of which is attached to this amendment and incorporated into the agreement by this reference.
3. **All other terms and conditions of the agreement dated January 12, 2015, between the County and Contractor shall remain in full force and effect.**

IN WITNESS WHEREOF, the parties hereto, by their duly authorized representatives, have affixed their hands.

COUNTY OF SAN MATEO

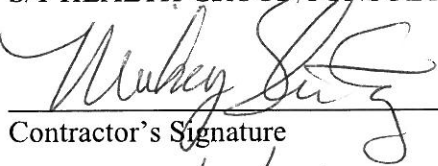
By: _____
President, Board of Supervisors, San Mateo County

Date: _____

ATTEST:

By: _____
Clerk of Said Board

S/T HEALTH GROUP CONSULTING, INC.



Contractor's Signature

Date: 1/19/2016

REVISED EXHIBIT A (REV. 1/12/16)

STATEMENT OF WORK 1 **COMPREHENSIVE 340B COMPLIANCE AND FINANCIAL AUDIT**

Statement of Work

The purpose of this Statement of Work is to define a project to be completed by STHG in collaboration with Rx|X Consulting, LLC (“Rx|X”) on behalf of San Mateo Medical Center with a comprehensive 340B audit that includes: an analysis of inventory and purchasing records for reconciliation of inpatient/outpatient 340B mixed use virtual inventory. An analysis of inventory and purchasing records for medications dispensed by San Mateo’s contracted pharmacies and replenished by Customer’s drug wholesaler on behalf of Customer in order to confirm the accuracy of inventory records showing the Customer’s inventory on hand in the contracted pharmacy, accuracy of vendor fees, review of purchasing history and accumulator program status; walk through of all eligibility, procurement, inventory, patient definition and Medicaid Billing practices and an assessment of the completeness and accuracy of current 340B policies and procedures.

The STHG/Rx|X partnership offers hospitals the most extensive review available in the 340B audit space. Their experience and involvement in several projects help hospitals diagnose and repair systemic issues in 340B operations.

At project’s end, San Mateo will receive a report with findings and recommendations designed to strengthen the integrity of its 340B Program and optimize program operations.

Project Plan

Mixed Use Audit and Contract Pharmacy Audit

STHG and Rx|X will review San Mateo’s 340B Program operations and compliance with program requirements from both a broad-based approach and a focused approach, respectively. The timing of the work will be concurrent and the final report will synthesize the entirety of the team’s findings and recommendations. More specifically, as the data is submitted to STHG for review, Rx|X will conduct its on-site review.

STHG’s audit approach is to review a large number of transactions to help identify:

- Potential system weaknesses in distinguishing inpatients from outpatients;
- Aberrant patterns in purchases versus 340B dispensing;
- Conversion issues between billing and purchase units;
- Inefficient accumulations due to limited Chargemaster to Accumulator maintenance;
- Inaccuracies in the contract pharmacy inventory or dispensing history;

Rx|X’s audit approach is to conduct a focused review of a sample of 65 patient-level dispensing history and compare the data to the medical record, provider files, OPA database, and cost report in mixed use, straight 340B and contract pharmacy settings. This is done to evaluate San Mateo’s compliance with meeting HRSA’s patient definition and preventing duplicate discounts.

Rx|X’s work complements STHG’s efforts by providing specific feedback on whether San Mateo has controls in place to ensure that 340B drugs go to proper patients from qualified providers and registered places of care both inside the system and through contract pharmacy relationships.

Rx|X will also evaluate the level of the hospital’s documentation of practices and gauge their readiness for a manufacturer or HRSA-audit.

Project Tasks

Mixed Use Audit TASK	TASK DESCRIPTION
1	Obtain and perform initial analysis of prime vendor wholesaler purchasing records for purchases made under the Federal 340B program where such 340B purchases are maintained in a mixed-use (virtual) inventory.
2	STHG will obtain and perform initial analysis of the San Mateo Medical Center “transaction log” of patient status from outpatient to inpatient status from the start date of (To Be Determined)
3	STHG will obtain and perform initial analysis of the San Mateo Medical Center pharmaceutical dispensing records for outpatients for the same time period described above.
4	STHG will obtain and perform initial analysis of San Mateo Medical Center virtual inventory accumulator program used to track mixed use virtual inventory for determining quantity of drugs to order under wholesaler accounts that access Federal 340B program pricing.

5	<p>STHG will perform a reconciliation between the dispensing records for San Mateo Medical Center outpatients, the drug purchases made under the wholesaler accounts established to access 340B program pricing and the mixed use virtual inventory accumulator program to include the following:</p> <p>Validating the identity and quantity of drugs dispensed to patients who were eligible to receive drugs at 340B program pricing, with patient eligibility to be determined by patient status as an outpatient at the time each drug dispense occurred, such eligibility to be determined by patient status in the San Mateo Medical Center patient transaction log.</p> <p>Excluding dispensing done to Medicaid outpatients in the calculation of 340B drug utilization eligibility, with determination of Medicaid status from the San Mateo Medical Center patient transaction log.</p> <p>Comparing the amount of each drug dispensed to 340B eligible outpatients to the quantity of purchases made for each drug under wholesaler accounts eligible to access 340B program pricing and comparing the net result of dispensing and purchasing to the net values remaining in the San Mateo Medical Center mixed use virtual inventory accumulator in order to verify appropriate purchasing patterns and accurate virtual inventory balances.</p> <p>Verifying that purchases made on accounts eligible to access 340B program pricing, as well as the virtual inventory accumulator values, are reflective of all drugs dispensed to eligible outpatients (excluding Medicaid patients as described above) and not limited to only those drugs for which 340B program pricing is available.</p>
6	Summarize reconciliation of inpatient/outpatient 340B mixed use virtual inventory, purchasing history and accumulator program status.

Contract Pharmacy Audits TASK	TASK DESCRIPTION
1	Obtain and perform initial analysis on contract pharmacy and wholesaler inventory and purchasing records for the defined audit period. Normalize data as needed.
2	Obtain and perform initial analysis of Customer's Pharmacy Department Clinic dispensing records by for the defined audit period. Normalize data as needed.
3	Develop analysis database and reporting tools.
4	Perform inventory reconciliation analysis, comparing reported inventory on hand by contracted pharmacy to wholesaler replenishment invoices and clinic dispensing records. Identify discrepancies between reported and calculated inventory on hand and discrepancies between invoiced quantities versus dispensed quantities. Define value of over/under discrepancies based on pricing reported for each time period in data provided by Customer.
5	Develop initial findings and perform quality assurance review

Compliance P&P, and Transaction Review TASK	TASK DESCRIPTION
1	<p>Covered Entity Eligibility: Rx X will:</p> <ul style="list-style-type: none"> • Review 340B eligibility criteria including the DSH percentage, contracts with state/local government or non-profit status, and attestations to the GPO exclusion and/or the orphan drug exclusion. • Examine the documentation for OPA registration (including the most recently filed cost report), and how the entity has registered its child sites (outpatient clinics) and ship-to/bill-to addresses, if applicable. • Map all locations where prescriptions originate for fill using 340B drugs, in-house or via a contract pharmacy and discuss how the other system sites relate to the 340B program, if applicable.
2	<p>GPO Exclusion: Assess compliance with the GPO exclusion through a review of wholesaler accounts, purchasing processes and inventory management systems, and interviews with billing/charge master staff.</p>
3	<p>Procurement and Distribution of 340B Drugs: During the site visit, Rx X will observe the process for 340B ordering and tracking and inventory management.</p>
4	<p>Contract Pharmacy Arrangements; Rx X will evaluate San Mateo’s 8 contract pharmacies’ compliance with 340B program requirements and OPA’s recommended essential elements of a contract pharmacy arrangement. As part of the detailed review, Rx X will perform patient-level transaction testing of approximately 30 contract pharmacy claims as part of the full service external audit offered by Rx X and STHG.</p>
5	<p>Patient Definition: Rx X will track the extent to which patients receiving 340B drugs meet all requirements of the patient definition as defined in 340B program regulations through sampled transaction testing. This step includes tracing a sample of approximately 35 prescription-based transactions from the patient, to provider and location eligibility, and evidence of responsibility of care. The sampled transactions will include 30 mixed use and straight 340B accounts and 5 high-cost drugs.</p>
6	<p>Prevention of Duplicate Discounts: Rx X will review the entity’s entry in OPA Medicaid Exclusion File, verify practices and appropriateness of Medicaid billing procedures for both pharmacy-dispensed and physician-administered drugs, and assess adherence to State billing policies for 340B drugs. As part of the transaction testing, Rx X will include a confirmation that billing practices adhere to the stated practices.</p>

Report Writing TASK	TASK DESCRIPTION
1	<ul style="list-style-type: none"> • Synthesize findings from STHG Mixed Use and Contract Pharmacy Audits and Rx X's Transaction Testing to develop findings and recommendations • Incorporate findings and recommendations from Rx X's review of policies and procedures and site visit
2	<ul style="list-style-type: none"> • Create Final Report
3	<ul style="list-style-type: none"> • Create and Deliver Presentation to San Mateo Pharmacy and Leadership • Create Implementation Plan for San Mateo Pharmacy

Post Audit Facilitation and Support

Rx|X will maintain its involvement with San Mateo post-assessment to assist the team with executing the recommendations from the report, supplying the team with essential policy updates on 340B, and collaborating on special 340B projects, if requested.

Assumptions

- STHG's project work will be accomplished primarily off-site via e-mail and internet communication unless included in a comprehensive Audit
- Project work will consist of analysis of purchasing and dispensing records provided to STHG by San Mateo Medical Center and will not include taking of any on site physical inventories.
- Data for this project will be provided by San Mateo Medical Center and will be in substantially the same file layout as provided in sample data given to S/T Health Group for the evaluation done to develop this task order.
- Rx|X project work to be performed on and off site.

Project Deliverables

At the end of the engagement, STHG will provide San Mateo with a 340B Program Review Report that includes the reconciliation results of inpatient/outpatient 340B mixed use virtual inventory, purchasing history and accumulator program status; transaction testing results; findings and recommendations on strengthening program integrity, a presentation to San Mateo Executives, and an Implementation Plan for the San Mateo Pharmacy Team.

Project Timeline

We will work with San Mateo on the optimal start / completion date, but notwithstanding scheduling conflicts, and once the required data is received by S/T Health Group, we anticipate this project would be completed within 8 -10 weeks.

Responsibilities and Obligations

Mutual obligations

San Mateo Medical Center and STHG will work together to insure successful management and completion of the project by meeting their obligations in the areas listed below.

San Mateo Medical Center Obligations

San Mateo Medical Center will provide a resource that will be responsible for guidance of the project, appointing appropriate San Mateo Medical Center resources, resolving project issues, and monitoring project progress.

In order to enable STHG staff to perform tasks in accordance with the project plan, San Mateo Medical Center will provide reasonable cooperation in providing support in the following areas:

- Access to San Mateo Medical Center data that may be required to complete project tasks.
- Reasonable access to San Mateo Medical Center staff as required for analysis, system documentation and training if needed.

In addition to providing reasonable cooperation and support, San Mateo Medical Center will meet payment obligations to STHG per the Agreement and as described in this task order.

STHG obligations

Overall responsibilities of STHG in this project are:

- Provide personnel with adequate skills to perform tasks as defined in this task order.
- Perform tasks on schedule and satisfy requirements for defined deliverables.
- STHG recognizes that during the term of this SOW and in the course of its performance, STHG will receive and otherwise be exposed to confidential information of San Mateo Medical Center. STHG acknowledges the confidential and secret character of the confidential information, and agrees that the confidential information is the sole, exclusive and extremely valuable property of San Mateo Medical Center. Accordingly, STHG agrees not to reproduce any of the confidential information except in the performance of this SOW, and not to divulge all or any part of the confidential information in any form to any third party, either during or after the term of this SOW.

Payment

Price

Accumulator Inventory Variance and Financial True-Up	\$ 52,000
On- Site Survey and Transaction Review	\$ 28,000

	Total \$80,000
Post Audit Facilitation and Support	Per hour rate \$ 300.00

STHG's proposed price for this project as described herein is \$80,000. Any travel and out-of-pocket expenses, with prior approval of San Mateo Medical Center, will be billed in addition to our fee and not to exceed \$3,000.

Should San Mateo Medical Center require any work previously completed and approved by San Mateo Medical Center to be redone, then San Mateo Medical Center will pay for all rework accomplished by STHG at rate of \$300 per hour, unless the reason for the work to be redone was caused by STHG.

Invoicing

S/T Health Group will invoice San Mateo Medical Center in the amount of \$32,000 upon execution of SOW 1. Invoicing of the remaining \$48,000 will be upon completion of project work. Invoice terms are net 30 days. Any changes to the estimated timeline or billing for this project will be pre-approved by San Mateo Medical Center.

Invoices will be approved by the Director of Pharmacy or their designee and paid within 30 days of receipt of invoice.

Invoices

All invoices must be emailed to the following email address:

SMMC-Accounts-Payable@smcgov.org

Processing time may be delayed if invoices are not submitted electronically.

Contractor is not entitled to payment for work not performed as required by this Agreement.

STATEMENT OF WORK 2
QUALITATIVE REVIEW OF PHARMACY CHARGE MASTER

Statement of Work

The purpose of this statement of work is to define a project to be completed by STHG to assist San Mateo Medical Center with an analysis and update of product information in the Pharmacy formulary file and San Mateo Medical Center charge master file, Pharmacy system and split billing system with the objective of making recommendations that San Mateo Medical Center can act upon to ensure accurate and appropriate patient billing for Pharmacy.

Project Scope and Tasks

TASK	TASK DESCRIPTION
1	Obtain 12 month purchase history data, normalize and perform preliminary analysis.
2	Obtain Pharmacy information system formulary file from the Pharmacy, Sentry software product table and San Mateo Medical Center information systems Pharmacy chagemaster CDM. Load and perform preliminary analysis
3	Compare 12 month wholesaler purchase history against Pharmacy, Sentry and CDM. Prepare recommendations for updating the primary national drug code number (NDC) based on current utilization history.
4	Compare Pharmacy, Sentry and CDM billing software by charge code to verify appropriate charge code mapping and relationships between systems.
5	Review CDM to verify HCPCS codes are current with CMS HCPCS requirements and OPPS APC payment increments - recommendations for updates as needed.
6	Review Pharmacy, Sentry and CDM conversion table (or other comparable conversion systems) to confirm correct charge increment conversions are in place for products with specific HCPCS increments in order to ensure correct billing increment transactions between Pharmacy transaction system and charge master.

Assumptions

1. Project work will be accomplished primarily off-site via e-mail and internet communication. Any visits onsite to San Mateo Medical Center by STHG will be by prior approval of San Mateo Medical Center and not to exceed \$3,000.00
2. The scope of work to be performed by STHG for this project does not include recommending patient prices.

Project Deliverables

- (1) NDC Recommendations to align the Pharmacy , Sentry and CDM with contemporaneous purchase data:
 - a. A report or electronic download indicating where the primary NDC number in the Pharmacy , Sentry and CDM should be updated based on the most commonly purchased NDC number in the review period.
 - b. A report of records that could not be reviewed because the generic entity reported in the billing detail could not be found in the purchasing data for the review period.
 - c. A report indicating any instances where STHG has identified if the NDC number currently being reported in the Pharmacy, Sentry and CDM is not appropriate for the charge code description.
- (2) Review of Pharmacy versus CDM
 - a. Recommendations for corrections where the product in the Pharmacy is not correctly aligned with the CDM.
 - b. Recommendations for corrections where the HCPCS code in the CDM is incorrect based on the product in the Pharmacy or if the HCPCS code is obsolete or incorrect.
 - c. Recommendations for corrections to any billing increment conversions tables that exist between the Pharmacy and the CDM.
- (3) Review of Pharmacy versus Sentry.
 - a. Recommendations for corrections where the product in the Pharmacy is not correctly aligned with the SENTRY.
 - b. Recommendations for corrections to any billing increment conversions tables that exist between the Pharmacy and the CDM.
- (4) Review of CDM versus SENTRY
 - a. Recommendations for corrections where items in the CDM are not correctly aligned with Sentry.
 - b. Recommendations for corrections to any billing increment conversions tables that exist between the CDM and Sentry.

Project Timeline

This statement of work will commence on or about (To Be Determined) with an estimated completion date of 10 weeks from receipt of all data required to complete the project as described herein.

Responsibilities and Obligations

Mutual Obligations

San Mateo Medical Center and STHG will work together to insure successful management and completion of the project by meeting their obligations in the areas listed below.

SAN MATEO MEDICAL CENTER Obligations

San Mateo Medical Center will provide a resource that will be responsible for guidance of the project, appointing appropriate San Mateo Medical Center resources, resolving project issues, monitoring project progress and approving deliverable acceptance.

In order to enable STHG staff to perform tasks in accordance with the project plan, San Mateo Medical Center will provide reasonable cooperation in providing support in the following areas:

- Access to San Mateo Medical Center data that may be required to complete project tasks.
- Reasonable access to San Mateo Medical Center staff as required for analysis, system documentation and training if needed.

In addition to providing reasonable cooperation and support, San Mateo Medical Center will meet payment obligations to STHG per the Agreement and as described in this statement of work.

STHG Obligations

Overall responsibilities of STHG in this project are:

- Provide personnel with adequate skills to perform tasks as defined in this statement of work.
- Perform tasks on schedule and satisfy requirements for defined deliverables.

Payment

Price

STHG's proposed price for this project as described herein is \$43,500.00 Any travel and out-of-pocket expenses, with prior approval of San Mateo Medical Center, will be billed in addition to STHG's fee and not to exceed 3,000.00.

Should San Mateo Medical Center require any work previously completed and approved by San Mateo Medical Center be redone, then San Mateo Medical Center will pay for all rework accomplished by STHG at rate of \$200 per hour, unless the reason for the work to be redone was caused by STHG.

Invoicing

STHG will present San Mateo Medical Center with an invoice for \$ 17,400.00 upon the execution of this statement of work. The remaining balance of \$ 26,100.00 will be due upon completion of project work. Invoice terms are Net 30 days. Any changes to the estimated timeline or billing for this project will be pre-approved by San Mateo Medical Center.

Any travel onsite to San Mateo Medical Center by STHG will be by prior approval of San Mateo Medical Center only. Any travel and out-of-pocket expenses for approved visits will be billed in conjunction with the final invoice.

Invoices will be approved by the Director of Pharmacy or their designee and paid within 30 days of receipt of the invoice.

Invoices

All invoices must be emailed to the following email address:

SMMC-Accounts-Payble@smcgov.org

Processing time may be delayed if invoices are not submitted electronically.

Contractor is not entitled to payment for work not performed as required by this Agreement.

STATEMENT OF WORK 3
MONTHLY CDM-NDC CHARGE MASTER MAINTENANCE

Statement of Work

The objective of this STATEMENT OF WORK 3 (SOW 3) is to provide San Mateo Medical Center with recommendations for the appropriate NDC number to be used in Hospital Pharmacy, Sentry and CDM in order to align NDC in formulary with contemporaneous purchasing trends.

Project Scope and Tasks

TASK	TASK DESCRIPTION
1	STHG will review contemporary purchasing records provided by San Mateo Medical Center's prime vendor wholesaler. STHG will normalize the purchasing data and apply our algorithms and resources to determine, by hospital, the predominant vendor product for each unique generic entity for the most recent review period.
2	The review period interval as defined by San Mateo Medical Center will be once per month. The selection criteria for each product as defined by San Mateo Medical Center will be the item most frequently ordered with the largest volume.
3	San Mateo Medical Center will provide STHG with an extract of the Hospital Pharmacy, Sentry and CDM. This data will contain the chargemaster (CDM) charge code, the associated NDC number and the hospital identifier. No patient specific data will be transferred.
4	STHG will compare, at a unique generic entity level, the NDC number currently on record for each charge code for each hospital and compare it to the purchasing records for each individual hospital to determine the appropriate NDC number for each charge code based on the recent purchasing history and the selection criteria pre-defined by San Mateo Medical Center.
5	Where the NDC of record in the hospital pharmacy system is different than the product identified in the review of the purchasing records, STHG will provide a report, by hospital, in a spreadsheet format, with a recommendation for updating the NDC number of record to the most current product.

Assumptions

1. Project work will be accomplished mostly off-site via internet and FTP transfer with occasional visits to San Mateo Medical Center corporate office as needed.
2. The scope of work to be performed by STHG for this project does not include advising San Mateo Medical Center on patient pricing used for items in the CDM.
3. The scope of this SOW 3 will be limited to purchasing data provided by San Mateo Medical Center's prime vendor wholesaler. Most hospital pharmacies also make limited direct purchases from other vendors and that data would not be included in this process. However, reports will be included to

San Mateo Medical Center of those items from the billing utilization for which a generic match in the purchasing data could not be found so that each hospital can take further action on those items.

4. San Mateo Medical Center will provide STHG with the data elements needed to provide the deliverables as defined in this SOW 3 including working with San Mateo Medical Center's prime vendor wholesaler to ensure timely delivery of purchasing data and working with San Mateo Medical Center's information systems department to assure timely delivery of billing interface data.

Project Deliverables

1. A report for San Mateo Medical Center will be delivered once per month, indicating where the primary NDC number in the hospital pharmacy system for each CDM number should be updated based on the most commonly purchased NDC number in each generic entity for the prior month.
2. A report of records that could not be reviewed because the generic entity reported in the billing detail could not be found in the purchasing data for the review period.
3. A report indicating any instances where STHG has identified if the NDC number currently being reported from the Pharmacy, Sentry and CDM is not appropriate for the CDM charge code description.

Project Timeline

The term of this SOW 3 shall commence on (To Be Determined) and shall continue in accordance with the terms of the Agreement, with **deliverables** provided once per month as defined in this task order.

Thereafter, San Mateo Medical Center may renew this SOW 3 in one year increments with STHG reserving the right to adjust the monthly fee to a maximum increase of 5% per year in any subsequent years.

Termination

This SOW 3 is non-terminable during the first 12 months. After the 1st anniversary of this agreement, either party may terminate the agreement with or without cause. A 30-day termination notice should be submitted in writing by either party.

Location

Project work will be accomplished primarily at STHG offices in Stafford, Texas. Site visits to the San Mateo Medical Center corporate office will be on an as-needed basis at the request of San Mateo Medical Center.

Fees and Expenses

STHG will provide the services and deliverables described above to San Mateo Medical Center for a fee of \$7,400 per month for the term of the agreement. Thereafter, San Mateo Medical Center may renew this SOW 3 in one year increments with STHG reserving the right to adjust the monthly fee to a maximum increase of 5% per year in any subsequent years.

Travel and out-of-pocket expenses, with prior approval of San Mateo Medical Center, will be billed in addition to the monthly fee and not to exceed \$3,000.00.

Invoices will be approved by the Director of Pharmacy or their designee and paid within 30 days of receipt of invoice.

Invoices

All invoices must be emailed to the following email address:

SMMC-Accounts-Payable@smcgov.org

Processing time may be delayed if invoices are not submitted electronically.

Contractor is not entitled to payment for work not performed as required by this Agreement.