AGREEMENT BETWEEN THE COUNTY OF SAN MATEO AND SAFEWAY INC.

THIS AGREEMENT, entered into this _____ day of June, 2013, by and between the COUNTY OF SAN MATEO, hereinafter called "County," and SAFEWAY 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;

WHEREAS, it is necessary and desirable that Contractor be retained for the purpose of providing comprehensive pharmacy services (including but not limited to dispensing, recordkeeping, drug utilization review, formulary management, patient profile, patient counseling, medication therapy management services, and other clinical pharmacy services) relating to County's participation in the 340B drug program to patients of the County's San Mateo Medical Center and its Clinics.

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

1. Exhibits and Attachments

The following exhibits and attachments are included hereto and incorporated by reference herein:

Exhibit A—Services, Payments, and Rates (including Attachments thereto)
Exhibit E – Corporate Compliance SMMC Code of Conduct (Third Parties)
Attachment I—§504 Compliance

2. Services to be Performed by Contractor

In consideration of the payments set forth herein and in **Exhibit A**, Contractor shall perform services for County in accordance with the terms, conditions and specifications set forth herein and in **Exhibit A.**

3. Payments

In consideration of the services provided by Contractor in accordance with all terms,

conditions and specifications set forth herein and in **Exhibit A,** County shall make payment to Contractor based on the rates and in the manner specified in **Exhibit A.** In no event shall the County's total fiscal obligation under this Agreement exceed TWO-MILLION NINE-HUNDRED SEVENTY-NINE THOUSAND DOLLARS ($2,979,000.00).

4. Term and Termination

Subject to compliance with all terms and conditions, the term of this Agreement shall be from July 1, 2013 through June 30, 2016.

This Agreement may be terminated by Contractor, the Chief of the Health System or his/her designee at any time without a requirement of good cause upon thirty (30) days' written notice to the other party.

In the event of termination, all finished or unfinished documents, data, studies, maps, photographs, reports, and materials (hereafter referred to as materials), if any, prepared by Contractor under this Agreement shall become the property of the County and shall be promptly delivered to the County. Upon termination, the Contractor may make and retain a copy of such materials. Subject to availability of funding, Contractor shall be entitled to receive payment for work/services provided prior to termination of the Agreement. Such payment shall be that portion of the full payment which is determined by comparing the work/services completed to the work/services required by the Agreement.

5. Availability of Funds

The County may terminate this Agreement or a portion of the services referenced in the Attachments and Exhibits based upon unavailability of Federal, State, or County funds, by providing written notice to Contractor as soon as is reasonably possible after the County learns of said unavailability of outside funding.

6. Relationship of Parties

Contractor agrees and understands that the work/services performed under this Agreement are performed as an independent Contractor and not as an employee of the County and that Contractor acquires none of the rights, privileges, powers, or advantages of County employees.

7. Hold Harmless

a. It is agreed that Contractor shall defend, hold harmless, and indemnify County and its officers, employees, agents, and servants from any and all claims, suits, or actions of every name, kind, and description brought by a third party which arise out of the terms and conditions of this Agreement and which result from the

negligent (or malicious/reckless) acts or omissions of Contractor and/or its officers, employees, agents, and servants.

b. Contractor shall defend, hold harmless, and indemnify County from and against any and all claims for wages, salaries, benefits, taxes, and all other withholdings and charges payable to, or in respect to, Contractor's representatives for services provided under this Agreement.

c. It is agreed that County shall defend, save harmless, and indemnify Contractor and its officers, employees, agents, and servants from any and all claims, suits, or actions of every name, kind, and description brought by a third party which arise out of the terms and conditions of this Agreement and which result from the negligent (or malicious/reckless) acts or omissions of County and/or its officers, employees, agents, and servants.

d. The duty of each party to defend, hold harmless, and indemnify the other as set forth herein shall include the duty to defend as set forth in Section 2778 of the California Civil Code.

e. In the event of concurrent negligence (or malicious/reckless acts) of County and/or its officers, employees, agents, and servants, on the one hand, and Contractor and/or its officers, employees, agents, and servants, on the other hand, then the liability for any and all claims for injuries or damage to persons and/or property which arise out of terms and conditions of this Agreement shall be apportioned according to the California theory of comparative negligence.

8. Assignability and Subcontracting

Contractor shall not assign this Agreement or any portion thereof to a third party or subcontract with a third party to provide services required by contractor under this Agreement without the prior written consent of County. Any such assignment or subcontract without the County's prior written consent shall give County the right to automatically and immediately terminate this Agreement.

9. Insurance

The Contractor shall not commence work or be required to commence work under this Agreement unless and until all insurance required under this Section has been obtained and such insurance has been approved by Risk Management, and Contractor shall use diligence to obtain such insurance and to obtain such approval. The Contractor shall furnish the County with certificates of insurance evidencing the required coverage, and there shall be a specific contractual liability endorsement extending the Contractor's coverage to include the contractual liability assumed by the Contractor pursuant to this Agreement. These certificates shall specify or be endorsed to provide that thirty (30) days' notice must be given, in writing, to the

County of any pending change in the limits of liability or of any cancellation or modification of the policy. Contractor shall at its own expense maintain the insurance coverage required by this Section.

A. *Worker's Compensation and Employer's Liability Insurance.* The Contractor shall have in effect during the entire life of this Agreement Workers' Compensation and Employer's Liability Insurance providing full statutory coverage. In signing this Agreement, the Contractor certifies, as required by Section 1861 of the California Labor Code, that it is aware of the provisions of Section 3700 of the California Labor Code which requires every employer to be insured against liability for Worker's Compensation or to undertake self-insurance in accordance with the provisions of the Code, and I will comply with such provisions before commencing the performance of the work of this Agreement.

B. *Liability Insurance.* The Contractor shall take out and maintain during the life of this Agreement such Bodily Injury Liability and Property Damage Liability Insurance as shall protect him/her while performing work covered by this Agreement from any and all claims for damages for bodily injury, including accidental death, as well as any and all claims for property damage which may arise from contractors operations under this Agreement, whether such operations be by himself/herself or by any subcontractor or by anyone directly or indirectly employed by either of them. Such insurance shall be combined single limit bodily injury and property damage for each occurrence and shall be not less than the amount specified below.

Such insurance shall include:

(1)	Comprehensive General Liability	$1,000,000 per incident $3,000,000 in aggregate
(2)	Motor Vehicle Liability Insurance	$1,000,000
(3)	Professional Liability	$1,000,000

County and its officers, agents, employees and servants shall be named as additional insured on any such policies of insurance, which shall also contain a provision that the insurance afforded thereby to the County, its officers, agents, employees and servants shall be primary insurance to the full limits of liability of the policy, and that if the County or its officers and employees have other insurance against the loss covered by such a policy, such other insurance shall be excess insurance only.

In the event of the breach of any provision of this section, or in the event any notice is received which indicates any required insurance coverage will be diminished or canceled, the County of San Mateo at its option, may, notwithstanding any other provision of this Agreement to the contrary, immediately declare a material breach of this Agreement and suspend all further work pursuant to this Agreement.

10. Compliance with Laws; Payment of Permits/Licenses

All services to be performed by Contractor pursuant to this Agreement shall be performed in accordance with all applicable Federal, State, County, and municipal laws, including, but not limited to, Health Insurance Portability and Accountability Act of 1996 (HIPAA) and all Federal regulations promulgated thereunder, as amended, and the Americans with Disabilities Act of 1990, as amended, and Section 504 of the Rehabilitation Act of 1973, as amended and attached hereto and incorporated by reference herein as Attachment "I," which prohibits discrimination on the basis of handicap in programs and activities receiving any Federal or County financial assistance. Such services shall also be performed in accordance with all applicable ordinances and regulations, including, but not limited to, appropriate licensure, certification regulations, provisions pertaining to confidentiality of records, and applicable quality assurance regulations.

Without limiting the generality of the foregoing, the parties agree to use patient specific information only for permitted treatment, billing and related record-keeping purposes, and to protect patient-specific information from unnecessary disclosure to persons not employed or contracted for by the parties, and from their own employees and contractors unless they have a need to know and agree to maintain the confidentiality of patient specific information. In the event that any patient information created, maintained or transmitted in connection with this agreement is to be transmitted electronically, the Parties agree that they shall comply in all respects with the requirements of HIPAA governing electronic transmission of individually identifiable patient information. See 42 CFR Section 160 et seq. Failure by either party to abide by these requirements shall be a basis for immediate termination of this agreement.

Further, Contractor certifies that the Contractor and all of its subcontractors will adhere to all applicable provisions of Chapter 4.106 of the San Mateo County Ordinance Code, which regulates the use of disposable food service ware.

In the event of a conflict between the terms of this Agreement and State, Federal, County, or municipal law or regulations, the requirements of the applicable law will take precedence over the requirements set forth in this Agreement.

Contractor will timely and accurately complete, sign, and submit all necessary documentation of compliance.

11. Non-Discrimination and Other Requirements

A. *Section 504 applies only to Contractors who are providing services to members of the public.* Contractor shall comply with § 504 of the Rehabilitation Act of 1973, which provides that no otherwise qualified handicapped individual shall,

solely by reason of a disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination in the performance of this Agreement.

B. *General Non-Discrimination.* No person shall, on the grounds of race, color, religion, ancestry, gender, age (over 40), national origin, medical condition (cancer), physical or mental disability, sexual orientation, pregnancy, childbirth or related medical condition, marital status, or political affiliation be denied any benefits or subject to discrimination under this Agreement.

C. *Equal Employment Opportunity.* Contractor shall ensure equal employment opportunity based on objective standards of recruitment, classification, selection, promotion, compensation, performance evaluation, and management relations for all employees under this Agreement. Contractor's equal employment policies shall be made available to County of San Mateo upon request.

D. *Violation of Non-Discrimination Provisions.* Violation of the non-discrimination provisions of this Agreement shall be considered a breach of this Agreement and subject the Contractor to penalties, to be determined by the County Manager, including but not limited to:

(1) termination of this Agreement
(2) disqualification of the Contractor from bidding on or being awarded a County contract for a period of up to 3 years
(3) liquidated damages of $2,500 per violation
(4) imposition of other appropriate contractual and civil remedies and sanctions, as determined by the County Manager

To effectuate the provisions of this section, the County Manager shall have the authority to examine Contractor's employment records with respect to compliance with this section and/or to set off all or any portion of the amount described in this section against amounts due to Contractor under the Contract or any other Contract between Contractor and County.

Contractor shall report to the County Manager the filing by any person in any court of any complaint of discrimination or the filing by any person of any and all charges with the Equal Employment Opportunity Commission, the Fair Employment and Housing Commission or any other entity charged with the investigation of allegations within 30 days of such filing, provided that within such 30 days such entity has not notified Contractor that such charges are dismissed or otherwise unfounded. Such notification shall include the name of the complainant, a copy of such complaint, and a description of the circumstance. Contractor shall provide County with a copy of their response to the Complaint when filed.

E. *Compliance with Equal Benefits Ordinance.* With respect to the provision of employee benefits, Contractor shall comply with the County Ordinance which prohibits contractors from discriminating in the provision of employee benefits between an employee with a domestic partner and an employee with a spouse.

F. *The Contractor shall comply fully with the non-discrimination requirements required by 41 CFR 60-741.5(a), which is incorporated herein as if fully set forth.*

12. Compliance with Contractor Employee Jury Service Ordinance

Contractor shall comply with the County Ordinance with respect to provision of jury duty pay to employees and have and adhere to a written policy that provides that its employees shall receive from the Contractor, on an annual basis, no less than five days of regular pay for actual jury service in San Mateo County. The policy may provide that employees deposit any fees received for such jury service with the Contractor or that the Contractor deducts from the employees' regular pay the fees received for jury service.

13. Retention of Records, Right to Monitor and Audit

A. Contractor shall maintain all required records for three (3) years after the County makes final payment and all other pending matters are closed, and shall be subject to the examination and/or audit of the County, a Federal grantor agency, and the State of California.

B. *Reporting and Record Keeping.* Contractor shall comply with all program and fiscal reporting requirements set forth by appropriate Federal, State and local agencies, and as required by the County.

C. Contractor agrees to provide to County, to any Federal or State department having monitoring or review authority, to County's authorized representatives, and/or their appropriate audit agencies upon reasonable notice, access to and the right to examine all records and documents necessary to determine compliance with relevant Federal, State, and local statutes, rules and regulations, and this Agreement, and to evaluate the quality, appropriateness and timeliness of services performed.

14. Merger Clause

This Agreement, including the Exhibits attached hereto and incorporated herein by reference, constitutes the sole Agreement of the parties hereto and correctly states the rights, duties, and obligations of each party as of this document's date. In the event that any term, condition, provision, requirement or specification set forth in this

body of the Agreement conflicts with or is inconsistent with any term, condition, provision, requirement or specification in any exhibit and/or attachment to this Agreement, the provisions of this body of the Agreement shall prevail. Any prior Agreement, promises, negotiations, or representations between the parties not expressly stated in this document are not binding. All subsequent modifications shall be in writing and signed by the parties.

15. Controlling Law and Venue

The validity of this Agreement and of its terms or provisions, as well as the rights and duties of the parties hereunder, the interpretation, and performance of this Agreement shall be governed by the laws of the State of California. Any dispute arising out of this Agreement shall be venued either in the San Mateo County Superior Court or the United States District Court for the Northern District of California.

16. Notices

Any notice, request, demand, or other communication required or permitted hereunder shall be deemed to be properly given when both (1) transmitted via facsimile to the telephone number listed below and (2) either deposited in the United States mail, postage prepaid, or when deposited for overnight delivery with an established overnight courier that provides a tracking number showing confirmation of receipt for transmittal, charges prepaid, addressed to:

If to County:
Chief Executive Officer
San Mateo Medical Center
222 W/ 39th Avenue
San Mateo, CA 94403
Facsimile: 650/573-2950

With copy to:
County Counsel's Office
400 County Center
Redwood City, CA 94063
Facsimile: 650/363-4034

If to Contractor:
Safeway Inc.
5918 Stoneride Mall Road
Pleasanton, CA 94588
Attn:
Title:
Facsimile: 623-687-2464

With copy to: Safeway Inc.
5918 Stoneridge Mall Road
Pleasanton, CA 94588
Attn: Legal Department

In the event that the facsimile transmission is not possible, notice shall be given both by United States mail and an overnight courier as outlined above.

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

COUNTY OF SAN MATEO

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

Date:_____

ATTEST:

By:_____
Clerk of Said Board

SAFEWAY INC.

_____
Contractor's Signature

Date: 5/30/2013

EXHIBIT A—SERVICES, PAYMENTS, AND RATES

THIS AGREEMENT is made by and between the County of San Mateo, a political subdivision of the State of California, (hereinafter "COVERED ENTITY"), and Safeway, Inc., a Delaware corporation, with licensed pharmacies as listed in Attachment B (hereinafter "Pharmacy").

WHEREAS, Covered Entity is a "Covered Entity" as defined in Section 340B of the Public Health Service Act (hereinafter "Section 340B") and is eligible to purchase certain outpatient drugs at reduced prices for use by Eligible Patients, as defined in this Agreement, from drug manufacturers who have signed a drug purchasing agreement with the United States Department of Health and Human Services (hereinafter "DHHS") and/or the manufacturers' wholesalers;

WHEREAS, Covered Entity provides health care services to Eligible Patients at Covered Entity eligible sites listed on Attachment A (each, the "Covered Entity Site", collectively "Covered Entity Sites");

WHEREAS, Covered Entity has engaged Sentry Data Systems, Inc. ("Sentry") to administer the Section 340B pharmacy benefits management services and pharmacy relationships of the Covered Entity with respect thereto;

WHEREAS, Pharmacy is duly licensed as a retail pharmacy in the State of California; and

WHEREAS, Covered Entity desires to engage Pharmacy to provide Pharmacy Services, as defined in this Agreement, to Eligible Patients with respect to outpatient drugs purchased pursuant to Section 340B.

NOW, THEREFORE, the parties agree as follows:

1. **Eligible Patients.** An individual will be considered an Eligible Patient under this Agreement if the following conditions are met:

(a) Covered Entity has established a relationship with the individual, such that Covered Entity maintains records of the individual's health care;

(b) The individual receives health care services from a health care professional who is either employed by Covered Entity or under contractual or other arrangements (e.g., referral for consultation) with Covered Entity such that the responsibility for the care provided remains with Covered Entity; and

(c) The individual receives health care services at the Covered Entity Site.

An individual will not be considered an Eligible Patient if the only health care service provided by Covered Entity to the individual is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting. Notwithstanding the foregoing, individuals registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the Public Health Services Act are considered Eligible Patients.

2. Sentrexed Drugs. "Sentrexed Drugs" are prescription outpatient drugs covered by this Agreement that: (i) are processed as either a 340B eligible transactions or non-340B transactions, (ii) do not include non-prescription drugs, subject to the applicable law in a particular state, (iii) met all eligibility requirements (such as eligible drug, eligible patient, eligible physician), and (iv) were marked by Sentry as processed under all contractual obligations.

3. Claims, Invoicing, Payment and Replenishment of Drugs. Claims, invoicing, payment and drug replenishment shall occur as follows:

(a) **Claims Processing.** All claims must be submitted in a NCPDP-compliant format and the Pharmacy is solely responsible for any claims switching or batch file claims submission costs.

i. Third-Party Claims: Pharmacy agrees to have copies all of its "non-Medicaid fee for service" third-party claims submitted to Sentrex.

ii. Cash Claims: For claims without third-party insurance coverage ("Cash Claims"), Pharmacy agrees to submit all such Cash Claims to Sentrex using a Sentrex-generated BIN and PCN. For Cash Claims determined to be:

1. 340B-eligible, Sentrex will calculate the ingredient costs, dispensing fee and other appropriate fees as determined by Covered Entity, and

2. not 340B-eligible, Sentrex will return the Pharmacy's submitted usual and customary price.

3. Covered Entity is responsible for the accuracy of the information returned to Pharmacy and Pharmacy shall have the right to rely on all such information. Covered Entity shall not later deny or revoke payment based on incomplete or inaccurate information provided by PBM to Pharmacy at the point of sale.

(b) **Invoices and Payments.**

i. On the 1st and 15th of each month, Sentry shall prepare and electronically deliver to Pharmacy an invoice which identifies all monies owed by Pharmacy to Covered Entity ("Invoice").

ii. A third-party paid claim will be included in the Invoice only if there are enough third- party claims that satisfy 3(a)(ii)(1) above that, either alone or when combined together, they equal or exceed one (1) Unit of Issuance based upon the National Drug Code ("NDC") number associated with the paid claim(s).

iii. A Cash Claim will be included in the Invoice only if it satisfies the following criteria: there are enough Cash Claims that either alone or when combined together with other Cash Claims, equal or exceed one (1) Unit of Issuance based upon the NDC number associated with the paid claim(s). Claims not satisfying such criteria will continue to accumulate and carry over to subsequent invoice period(s).

iv. For each 340B-eligible claim, Pharmacy shall owe Covered Entity an amount equal to the combined patient co-payment plus any third-party payments less the 340B Dispensing Fee as determined by Attachment C herein.

v. Within 30 business days of Pharmacy's receipt of the Invoice, Pharmacy shall remit payment thereof by electronic funds transfer to Covered Entity, at which time Sentry shall be notified of such payment by Pharmacy and Covered Entity.

vi. Sentrex will re-examine all claims that have been processed for four (4) invoicing period(s). If additional eligibility information has become available to make a previous ineligible claim now 340B eligible, Sentrex will add the additional 340B eligible claims from agreed upon previous invoicing period(s) to the current invoicing period.

(c) **Inventory Replenishment.**

i. Three (3) times a week, Sentrex shall order, for delivery to Pharmacy all drugs due to be replenished.

ii. Pharmacy acknowledges that dispensed medications will only be replenished if they have reached their replenishment point (full package unit) and thirty (30) days have passed since a third- party claim was successfully adjudicated. Replenishment will be based upon the specific NDC dispensed.

iii. Controlled substances (non CII) are included in the Sentrex system, which reconciles the account. Controlled substances (non CII) will be replenished the same way as non-controlled substances.

iv. CIIs are excluded from the 340B program.

v. *Slow Moving Items*. Any drug that is dispensed that does not meet a unit of issuance within 120 days of oldest dispensation will be reconciled on the following invoice. Any drug that has been dispensed that crosses a package boundary and subsequently becomes a slow mover will be reconciled on a yearly basis according the closeout procedure outlined in section (d) below.

vi. *Slow Moving Partial Packages*. Drugs are dispensed by billing units but purchased in manufacturer specified package sizes. At times, a part of a prescription will cross a package size boundary causing part of the prescription to be replenished but not the full prescription. For example: a package sized at 100 tablets is used to replenish 2 prescriptions for 60 tablets each (total of 120 tablets for both prescriptions). Both prescriptions are invoiced, 100 are immediately replenished, and the rest wait for enough subsequent claims to arrive until they can be replenished. If the portion of a claim that is already invoiced does not meet a unit of issuance within 120 calendar days of dispensation agreed in section B.10., above, the un-replenished portion of the prescription will be reconciled on the subsequent invoice. Covered Entity will remit payment to the Pharmacy for the amounts of the drugs in question at the Wholesale Acquisition Cost ("WAC") for the NDC for that particular drug, prorated according to the amount of drugs that cannot be replenished.

vii. For all out-of-stock drugs ("OOS") drugs owed by Covered Entity to Pharmacy, Sentrex will reorder these OOS drugs onto the next inventory replenishment order. If, however, after two (2) consecutive invoice periods, the drug(s) remain OOS, Covered Entity will credit back the full amount associated with the claims that comprised the OOS drug order. Such credit amounts will be "negative" claim items on the third invoice following the original replenishment order date. For third- party claims, the full amounts remitted by Pharmacy to Covered Entity will be credited. For Cash Claims, Pharmacy shall be credited an amount equal to the Wholesaler Acquisition Cost ("WAC") of the OOS drug(s), prorated according to the amount of drugs that cannot be replenished.

viii. *Discontinued or Changed NDCs*. Periodically, pharmaceutical manufacturers will discontinue or change certain NDCs. Sentrex will periodically inform the Pharmacy of any such changes in order to prevent replenishment opportunity from accumulating for NDCs that cannot be replenished. In the event that 340B eligible third-party claims are adjudicated for a discontinued NDC, Sentry will remove such claims from 340B consideration on future billing periods. The Pharmacy will need to correct the adjudication of said NDCs, and should do so immediately. In the event that 340B eligible claims are adjudicated for a discontinued NDC which cannot be reversed,

Sentrex will attempt to replenish said NDCs, and if unsuccessful, the following procedure will be used to reconcile the inventory:

1. Sentrex will generate an over/under replenishment status inventory report;

2. For each un-replenishable item, Covered Entity will remit payment to the Pharmacy for the amounts of the drugs in questions at Wholesaler Acquisition Cost ("WAC") for the package size as defined by the NDC for that particular drug.

ix. *Pending Inventory*. Covered Entity, via Sentrex, shall provide Contract Pharmacy an outstanding inventory report.

x. *Switch Fees*. Pharmacy will be responsible to pay any and all switch fees associated with the provision of claims required to verify 340B eligibility.

(d) **Close out and Final Reconciliation.**

Shutdown Procedure. In the event that a Pharmacy decides to sever its contractual relationship with Covered Entity or vice versa, the following shutdown procedure must be utilized:

i. Sentrex will generate an over/under replenishment status inventory report;

ii. for all over-replenished items, the Pharmacy must send the correct number of drugs back to Covered Entity if the Covered Entity is also a Sentinel RCM customer; if the Covered Entity is not a Sentinel RCM customer, Pharmacy must destroy all over-replenished 340B drugs;

iii. Sentrex will prepare a last invoice on behalf of Covered Entity to the Pharmacy;

iv. Sentrex will place a last replenishment order to the Drug Wholesaler for Pharmacy on behalf of Covered Entity;

v. for under-replenished items, Covered Entity will remit payment to the Pharmacy for the amounts of the drugs in question at WAC. NOTE: WAC pricing must be supplied by the Pharmacy. AWP prices are provided on an Excel spreadsheet strictly for reference and are not WAC prices.

(e) The parties understand and agree that time is of the essence with respect to subparagraphs (b)(i) and (b)(v) of this Section 3.

4. Sentrex Claims Tracking System. The parties to this Agreement understand that, pursuant to Section 340B, Covered Entity is liable to the manufacturer of Sentrexed Drugs in an amount equal to the reduction in the price of Sentrexed Drugs in the event that a discounted Sentrexed Drug is sold or otherwise transferred to a person who is not an Eligible Patient. Covered Entity, with the assistance of Sentry and Pharmacy, shall establish and maintain an Eligible Patient pharmacy claims tracking system suitable to prevent the diversion of Sentrexed Drugs to individuals who are not Eligible Patients. Covered Entity acknowledges and agrees that it shall be fully responsible for verification of patients' eligibility to Pharmacy and for maintaining such tracking system on Pharmacy's behalf. Covered Entity may establish a process for periodic random (sample) comparison of its prescribing records with Pharmacy's dispensing records to detect potential irregularities. Said comparison may be conducted quarterly and comparison of purchasing and dispensing records may be performed every six months. Pharmacy will permit Covered Entity or its duly authorized representatives to have reasonable access to Pharmacy's facilities and records during the term of this Agreement in order to make periodic checks regarding the efficiency of the tracking systems.

5. Prescriptions.

If cash claim, pharmacy shall dispense Sentrexed Drugs only in the following circumstances:

(a) Upon receipt of a "Paid" pharmacy claim response from Sentrex for an Eligible Patient, which "Paid" response shall verify that the patient is eligible, that the drug is a Sentrexed Drug, and receipt of the amount, if any, of the patient's copay.

6. Pharmacy Services. Pharmacy shall provide the following services ("Pharmacy Services"):

(a) Dispensing Sentrexed Drugs to Eligible Patients in accordance with all applicable State and Federal statutes and regulations and the professional judgment of the dispensing pharmacist;

(b) Participating in Sentrex pre- and post-adjudication programs pursuant to the terms of this Agreement and as reasonably directed by Covered Entity or Sentry in order to establish or verify costs, charges, reimbursement rates, billing, payments or receipts;

(c) Participating, where practicable for Pharmacy, in third-party payor arrangements in which the Covered Entity participates or which the Covered Entity may request. Pharmacy shall make commercially reasonable efforts to enter into all such

third-party payor arrangements prior to the Commencement Date and shall provide Covered Entity with a list of such plans upon request.

(d) Utilizing Pharmacy and Sentrex systems, maintaining all records and reports (including without limitation, prescription files, velocity reports and records of ordering and receipt) required under this Agreement, Section 340B, and by any applicable Federal and State law and regulations, which shall be accessible to Covered Entity, DHHS and the manufacturer/wholesaler in the case of audit in accordance with the terms of Section 14 of this Agreement. Such records shall be retained for not less than five (5) years after the Pharmacy Services are rendered, and shall be available for inspection or audit by Covered Entity and as otherwise permitted by law and by the terms of Section 14 of this Agreement;

(e) Conducting Eligible Patient drug utilization review;

(f) Providing drug-related information services to Covered Entity clinical personnel, consulting with Covered Entity on the purchase of Sentrexed Drugs, and identifying and disposing of Sentrexed Drugs in its inventory which are out of date;

(g) Maintaining Eligible Patient drug profiles;

(h) Counseling and advising Eligible Patients consistent with the rules, limitations, and privileges incident to the pharmacy-patient relationship;

(i) Provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services); and

(j) Proving other services to the Covered Entity or its patients at the option of the Covered Entity (e.g., home care, delivery, reimbursement services) as agreed upon by the parties, and regardless of the services provided by the Pharmacy, access to 340B pricing will always be restricted to patients of the Covered Entity.

7. Relationship of the Parties.

(a) Pharmacy is an independent contractor and shall be solely responsible for its acts and omissions regarding advice and services it is required to provide to Eligible Patients and Covered Entity. Pharmacy agrees to render all services provided under this Agreement in accordance with professional standards applicable to pharmacy services and in accordance with rules and regulations of the California State Board of Pharmacy. Pharmacy shall have the right to refuse to serve any Eligible Patient where such service would violate any statute, regulations, or professional standards applicable

to pharmacy services. Pharmacy shall notify Covered Entity of any refusal of service within twenty-four (24) hours of such refusal.

(b) Covered Entity agrees that it shall expend efforts on education and promotion of the benefits of utilizing Pharmacy to obtain discounts on Sentrexed Drugs, and Pharmacy acknowledges that such efforts shall be at Covered Entity's sole discretion. At Pharmacy's option, upon mutual agreement of the parties, Pharmacy may work with Covered Entity in such efforts.

(c) By signing this Agreement, Covered Entity confirms that Sentry is authorized to act as Covered Entity's agent with respect to administering 340B pharmacy benefits management services and the relationship with Pharmacy. Accordingly, Pharmacy acknowledges that Sentry is and will act as agent for Covered Entity. Notwithstanding anything herein to the contrary, Sentry is not authorized to amend this Agreement or change the economic terms of this Agreement. Nothing herein shall prohibit Covered Entity from communicating directly with Pharmacy at any time. In the event of a conflict between instructions given to Pharmacy by Covered Entity and instructions given to Pharmacy by Sentry, Covered Entity's instructions shall control.

8. Pharmacy Site(s). Pharmacy agrees it will provide Pharmacy Services contracted for under this Agreement at the site(s) listed on Attachment B.

9. Payment for Pharmacy Services. Pharmacy shall be timely paid through the twice monthly invoice process established in 3(b) for Pharmacy Services in accordance with the terms provided on Attachment C to this Agreement. The parties have freely negotiated the terms of this Agreement and neither has offered or received any inducement or other consideration from the other party for entering into this Agreement. The compensation to be paid to Pharmacy is consistent with fair market value in arms-length transactions for Pharmacy Services and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under a Federal or State health care program. Nothing in this Agreement shall be construed to require Covered Entity to make referrals of patients to Pharmacy.

10. Pharmacy Dispensing Fee. The parties agree that Pharmacy shall receive a Dispensing Fee, as set forth in Attachment C, for each prescription of Sentrexed Drugs filled for Eligible Patients and that such Dispensing Fee covers Pharmacy's costs and constitutes the sole and exclusive payment Pharmacy is entitled to receive hereunder.

11. Patient Choice. Pharmacy understands and agrees that Eligible Patients of Covered Entity may elect not to use Pharmacy for Pharmacy Services. In the event that

an Eligible Patient elects not to use Pharmacy for such services, the patient may obtain the prescription from the prescriber and then obtain the drug(s) from the pharmacy provider of his or her choice.

12. Final Reconciliation Reports. Final reconciliation report shall occur no later than thirty (30) days from the date of termination of this Agreement. The provisions of this Section 12 shall survive the expiration or termination of this Agreement for any reason.

13. Prohibition on Resale or Transfer.

Covered Entity agrees that it will not resell or transfer a Sentrexed Drug to an individual who is not an Eligible Patient.

14. Audits.

(a) Pharmacy understands and agrees that both Pharmacy and Covered Entity are subject to audit by DHHS and by drug manufacturers who have signed a drug purchasing agreement with DHHS, which audits may pertain to the Covered Entity's compliance with the prohibition on drug resale or transfer and the prohibition on duplicate Medicaid rebates and discounts. Pharmacy further understands that the DHHS has published proposed guidelines for such audits, a copy of which is attached hereto as Attachment D. Pharmacy agrees to cooperate with such audits and to comply with applicable provisions of the audit guidelines and amendments thereto that may be published from time to time.

(b) Pharmacy grants Covered Entity, and its duly authorized representatives, including Sentry, the right, on behalf of Covered Entity, to audit its books and records, including all electronic records, to verify and ensure compliance with the duties, obligations and transactions outlined hereunder. Any such audit shall be conducted during reasonable business hours, upon reasonable prior written notice, and in a manner so as not to interfere with the conduct of Pharmacy's business. Pharmacy agrees to use commercially reasonable efforts to cooperate with such audits in good faith.

(c) Provisions of this Section 14 shall survive the expiration or termination of this Agreement for any reason.

15. Inspection by Manufacturer. Pharmacy and Covered Entity understand and agree that a copy of this Pharmacy Services Agreement will be provided, upon written request, to a drug manufacturer who has signed a purchasing agreement with DHHS and sells Sentrexed Drugs to Covered Entity. In the event either party hereto receives

such a request, it shall immediately inform the other party and each party shall then have the opportunity to delete any information in this Agreement and Attachments, which it considers to be proprietary and confidential prior to submitting the Agreement to the requesting manufacturer. The provisions of this Section 15 shall survive the expiration or termination of this Agreement for any reason.

16. Insurance. Pharmacy shall maintain during the term of this Agreement a policy of liability insurance with a responsible insurance carrier in an amount not less than $1,000,000 per incident and $3,000,000 in the aggregate and which includes the Sentrexed Drugs in its coverage.

Covered Entity shall obtain and maintain, at its expense for so long as this Agreement is in effect, a policy or policies of Commercial General Liability insurance including completed operations, personal and advertising injury and contractual liability coverage) covering Covered Entity, its directors, officers, employees, agents and representatives with minimum limits of $2,000,000 per occurrence/$4,000,000 aggregate, and Professional Liability insurance including Completed Operations coverage written on an occurrence form with minimum limits of $2,000,000 per occurrence/$4,000,000 aggregate. Each such policy shall be underwritten by insurers rated "A-" or better by A.M. Best Company. Covered Entity will provide Certificates of Insurance naming Pharmacy "Additional Insured," with respect to General Liability, Covered Entity shall provide such Certificates of Insurance upon Pharmacy's request.

17. Indemnification

(a) Indemnification for Professional Liability. When the law establishes a professional standard of care for Pharmacy's Services, to the fullest extent permitted by law, Pharmacy shall indemnify, protect, defend and hold harmless Covered Entity and any and all of its officials, employees and agents ("Indemnified Parties") from and against any and all losses, liabilities, damages, costs and expenses, including attorney's fees and costs to the extent same are caused in whole or in part by any negligent or wrongful act, error or omission of Pharmacy, its officers, agents, or employees (or any entity or individual that Pharmacy shall bear the legal liability thereof) in the performance of professional services under this Agreement.

(b) Indemnification for Other Than Professional Liability. Other than in the performance of professional services and to the full extent permitted by law, Pharmacy shall indemnify, defend and hold harmless Covered Entity and any and all of its employees, officials and agents from and against any liability (including liability for claims, suits, actions, arbitration proceedings, administrative proceedings, regulatory proceedings, losses, expenses or costs of any kind, whether actual, alleged or threatened, including attorneys fees and costs, court costs, interest, defense costs, and

expert witness fees), where the same arise out of, are a consequence of, or are in any way attributable to, in whole or in part, the performance of this Agreement by Pharmacy or by any individual or entity for which Pharmacy is legally liable, including but not limited to officers, agents, or employees of Pharmacy. Pharmacy's indemnification obligations under this paragraph 17(b) and under paragraph 17 (a) shall not apply to the extent that any losses, liabilities, damages, costs and expenses, including attorney fees and costs arise from the negligence or willful misconduct of Covered Entity or Covered Entity Indemnified Parties.

(c) Indemnification by Covered Entity. Covered Entity shall indemnify, defend and hold harmless Pharmacy and any and all of its directors, officers, employees, agents and representatives from and against any liability (including liability for claims, suits, actions, arbitration proceedings, administrative proceedings, regulatory proceedings, losses, expenses or costs of any kind, whether actual, alleged or threatened, including attorneys fees and costs, court costs, interest, defense costs, and expert witness fees), where the same arise out of, are a consequence of, or are in any way attributable to, in whole or in part, the performance of this Agreement by Covered Entity or by any individual or entity for which Covered Entity is legally liable, including but not limited to its officials, employees or agents.

18. Non-Assignment. This Agreement may not be assigned by either party without the prior written agreement of the other party, which agreement shall not be unreasonably delayed or withheld, provided, however, that either party may assign this Agreement to any successor-in-interest to which any of its facilities subject to this Agreement may be transferred.

19. Term and Termination.

(a) This Agreement shall commence as outlined by Section 4 of the Agreement and shall continue for a term of three (3) years thereafter unless terminated earlier as stated below in subsection 19(a)i. or 19(a)ii. or 19(a)iii.

i. Subject to Section 26, either party hereto, immediately upon written notice, in the event either party is unable to meet its obligations under this Agreement; or

ii. Either party hereto, immediately and without prior notice, upon a material breach of this Agreement if such breach cannot be cured, or upon 30 days prior written notice if such breach is not cured within such 30-day period. Without limiting Covered Entity's right to assert any other act or failure to act as constituting a material breach by Pharmacy, Pharmacy's knowingly dispensing a Sentrexed Drug to an

individual who is not an Eligible Patient or any other diversion of a Sentrexed Drug shall be deemed to be a material breach. Either party's waiver or failure to take action with respect to the other party's failure to comply with any term or provision of this Agreement shall not be deemed to be a waiver of the right to insist on future compliance with such term or provision.

iii. Either party may terminate this Agreement at its option upon 90 days written notice.

(b) Any notice required to be given pursuant to the terms and provisions of this Agreement shall be in writing and shall be sent by certified or registered mail, return receipt requested or by overnight delivery by a nationally recognized courier, to the parties at the addresses set forth on the signature pages hereto. Notice shall be effective on the day it is received.

(c) Upon the request of Covered Entity, Pharmacy agrees to continue to provide Pharmacy Services on the payment and other terms of this Agreement for a period of up to sixty (60) days after the date this Agreement expires or is terminated in order to ensure an effective transition of services and continuation of quality care for Eligible Patients.

20. Compliance With Laws. The parties hereto shall comply with all applicable federal, state and local laws, rules, regulations and requirements.

21. Choice of Law. This Agreement shall be interpreted according to the substantive laws of the State of California.

22. Representations of Pharmacy. Pharmacy represents to Covered Entity that:

(a) it employs, and will continue to employ throughout the term of this Agreement, sufficient qualified and credentialed personnel needed to manage and operate the Pharmacy and provide the services anticipated hereunder in a timely, professional, competent and ethical manner;

(b) it owns, possesses and employs, and will continue to employ throughout the term of this Agreement, sufficient technology and equipment as needed to manage and operate the Pharmacy and provide the services in the manner anticipated hereunder;

(c) it will render the services hereunder in accordance with prevailing pharmaceutical and medical standards that are applied in the same fashion to all patients of Covered Entity;

(d) it will render all services to Eligible Patients without regard to race, creed, color, age, sex, sexual orientation, citizenship, marital status, veteran status, national origin, disability, religion, arrest record or other protected status;

(e) it will not use drugs purchased under Section 340B to dispense Medicaid prescriptions, except as provided in an arrangement with the State Medicaid agency as approved by Covered Entity to prevent duplicate discounting and as required by law; and

(f) it understands that it is not permitted to, and shall not, disclose any information regarding Section 340B patient eligibility or pricing without the prior express written consent of Covered Entity.

23. Representations of Covered Entity and Pharmacy. Covered Entity and Pharmacy each represent to the other that:

(a) all of its employees, agents, representatives and members of its workforce, whose services may be used to fulfill obligations under this Agreement are or shall be appropriately informed of the terms of this Agreement and are under legal obligation, by contract or otherwise, sufficient to enable each of Covered Entity and Pharmacy to fully comply with all provisions of this Agreement including, without limitation, with respect to Pharmacy, the requirement that modifications or limitations that Covered Entity has agreed to adhere to with regards to the use and disclosure of Protected Health Information of any individual that materially affects and/or limits the uses and disclosures that are otherwise permitted will be communicated to Pharmacy, in writing, and in a timely fashion;

(b) they will reasonably cooperate with each other and with Sentry in the performance of the mutual obligations under this Agreement;

(c) the execution and delivery of this Agreement and the performance of the duties obligations and transactions contemplated do not and will not contravene, conflict with or violate any agreement, commitment, plan or instrument binding on Covered Entity or Pharmacy, including without limitation any participating provider agreement and any third party payor or pharmacy benefit management agreement; and

(d) neither they, nor their respective shareholders, members, directors, officers, agents, employees or members of its workforce have been excluded or served a notice of exclusion or have been served with a notice of proposed exclusion, or have committed any acts which are cause for exclusion, from participation in, or had any sanctions, or civil or criminal penalties imposed under, any federal or state healthcare program, including but not limited to Medicare or Medicaid, or have been convicted,

under federal or state law (including without limitation a plea of nolo contendere or participation in a first offender deterred adjudication or other arrangement whereby a judgment of conviction has been withheld), of a criminal offense related to (i) the neglect or abuse of a patient, (ii) the delivery of an item or service, including the performance of management or administrative services related to the delivery of an item or service, under a federal or state healthcare program, (iii) fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a healthcare item or service or with respect to any act or omission in any program operated by or financed in whole or in part by any federal, state or local government agency, (iv) the unlawful, manufacture, distribution, prescription or dispensing of a controlled substance, or (v) interference with or obstruction of any investigation into any criminal offense described in (i) through (iv) above. Each of Covered Entity and Pharmacy further agrees to notify the other immediately after it becomes aware that any of the foregoing representations and warranties may be inaccurate or may become incorrect and upon notice that it is being investigated in connection with any federal or state healthcare program.

24. Representations of Covered Entity. Covered Entity represents to Pharmacy that:

(a) it is a Covered Entity as defined in Section 340B and will remain such throughout the term of this Agreement; and

(b) it has the authority to enter into this Agreement and will perform its responsibilities hereunder in a professional and diligent manner consistent with industry standards reasonably applicable to the performance thereof.

25. HIPAA Compliance.

The parties acknowledge that each party is a "Covered Entity" as defined in the Health Insurance Portability and Accountability Act of 1996, as amended, title 45 Code of Federal Regulations section 160.103, and is acting in that capacity in performance of this Agreement.

26. Non-disclosure.

(a) Non-disclosure. In the course of performing under this Agreement, either of the parties may receive, be exposed to or acquire Confidential Information including but not limited to, all information, data, reports, records, summaries, tables and studies, whether written or oral, fixed in hard copy or contained in any computer data base or computer readable form, as well as any information identified as confidential of the other party ("Confidential Information"). Without limiting the foregoing, the parties

acknowledge and agree that this Agreement, including the pricing terms of this Agreement, constitutes Confidential Information. For purposes of this Agreement, Confidential Information shall not include Protected Health Information, the security of which is the subject of this Agreement and is provided for in each party's capacity as a Covered Entity in performance of this Agreement. The parties, including their respective employees, agents or representatives (i) shall not disclose to any third party the Confidential Information except as otherwise permitted by this Agreement, (ii) only permit use of such Confidential Information by employees, agents and representatives having a need to know in connection with performance under this Agreement, and (iii) advise each of their employees, agents, and representatives of their obligations to keep such Confidential Information confidential. Notwithstanding anything to the contrary herein, each Party shall be free to use, for its own business purposes, any ideas, suggestions, concepts, know-how or techniques contained in information received from each other that directly relates to the performance under this Agreement. This provision shall not apply to Confidential Information: (1) after it becomes publicly available through no fault of either Party hereto; (2) which is later publicly released by either Party hereto in writing; (3) which is lawfully obtained from third parties without restriction; or (4) which can be shown to be previously known or developed by either Party hereto independently of the other Party. The parties acknowledge that Covered Entity is subject to the California Public Records Act and that this Agreement shall be a matter of public record.

(b) Enforcement. Each of the parties acknowledges and agrees that any breach by it of any of the provisions of Sections 25(a) or 25(b) ("Restrictive Covenants") would result in irreparable injury and damage for which money damages would not provide an adequate remedy. Therefore, if either party hereto breaches, or threatens to commit a breach of, any of the Restrictive Covenants, the other party shall have the right and remedy (upon compliance with any necessary prerequisites imposed by law upon the availability of such remedy), which shall be independent and severally enforceable, and which shall be in addition to, and not in lieu of, any other rights and remedies available to it under law or in equity (including, without limitation, the recovery of damages), to have the Restrictive Covenants specifically enforced (without posting bond and without the need to prove damages) by any court having equity jurisdiction, including, without limitation, the right to an entry against breaching party of restraining orders and injunctions (preliminary, mandatory, temporary and permanent), without posting bond and without the need to prove damages, against violations, threatened or actual, and whether or not then continuing, of such covenants. The existence of any claim or cause of action by the breaching party, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement of the Restrictive

Covenants. In addition, any breach of the Restrictive Covenants shall constitute a material breach of this Agreement.

27. Force Majeure. Each Party's delay in, or failure of, performance under this Agreement shall be excused where such delay or failure is caused by an act of nature, fire or other catastrophe, electrical, computer, software, transmissions, communications or mechanical failure, work stoppage, or delays or failure to act of any carrier or agent, or any other cause beyond such Party's direct control.

28. Conflict of Interest. The Pharmacy is subject to all federal, state and local conflict of interest laws, regulations and policies applicable to public contracts and procurement practices Government Code sections 1090, et. Seq., and 81000, et. Seq. Pharmacy shall complete one or more statements of economic interest as described on [Attachment C - Pharmacy's Statement of Financial Interest] hereto which may be amended from time to time by Covered Entity. Upon Covered Entity's request, the Pharmacy shall submit the necessary supplementary documents to Covered Entity.

The Pharmacy shall establish and make known to it employees and agents appropriate safeguards to prohibit employees from using their positions for a purpose that is, or that gives the appearance of being, motivated by the desire for private gain for themselves or others, particularly those with whom they have family, business or other relationships.

The Pharmacy's personnel employed at any Covered Entity site shall not accept gratuities or any other favors from any party with whom the Pharmacy is dealing in the performance of this Agreement. In connection with any task in this Agreement, the Pharmacy shall not recommend or specify any product, supplier, or contractor with whom Pharmacy has a direct or indirect financial or organizational interest or relationship that would violate conflict of interest laws, regulation or policies.

29. Notices. Any notice required or permitted hereunder shall be given as outlined by Section 16 of the Agreement.

ATTACHMENT A TO EXHIBIT A
ELIGIBLE COVERED ENTITY SITES

Name, Address & OPA ID# of Facility
San Mateo Medical Center 222 West 39th Avenue San Mateo, CA 94403 (DSH050113)
San Mateo County Health Center 222 West 39th Avenue San Mateo, CA 94403 (CH091140)
San Mateo Medical Center Edison Clinic 222 West 39th Avenue San Mateo, CA 94403 STD 944039
San Mateo Medical Center Daly City Youth Health Center 2780 Junipero Serra Daly City, CA (CH09114D)
San Mateo Medical Center Fair Oaks Children's Clinic 630 Laurel Street Redwood City, CA (CH09114E)
San Mateo Medical Center North County Health Center 380 90th Street Daly City, CA (CH09114F)
San Mateo Medical Center Willow Clinic 795 Willow Road Menlo Park, CA (CH09114I)

Name, Address & OPA ID# of Facility
San Mateo Medical Center Fair Oaks Family Health Center[1] 2710 Middlefield Road Redwood City, CA (CH09114L)
San Mateo Medical Center Coastside Health Center 225 S Cabrillo Hwy #100A Half Moon Bay, CA (CH09114N)
San Mateo Medical Center South San Francisco Health Center 306 Spruce St. South San Francisco, CA (CH09114O)
San Mateo Medical Center Sequoia Teen Wellness Center 200 James Avenue Redwood City, CA (CH09114S)

This list may be changed by County/Covered Entity by providing written notice to Pharmacy/Contractor of any changes, and changes do not require an amendment of this Agreement or Exhibit.

[1] NOTE – In Fall 2013, the Fair Oaks Family Health Center name and location will change, but the number will remain the same.

ATTACHMENT B TO EXHIBIT A
CONTRACTED PHARMACY LOCATIONS

Name and Address
Safeway 0305 1071 EL Camino Real Redwood City, CA 94063 NCPDP: 0542173
Safeway 0964 4950 Mission St San Francisco, CA 94112 NCPDP: 0558241
Safeway 0747 850 Woodside Rd Redwood City, CA 94061 NCPDP: 0545410
Safeway 2719 525 EL Camino Real Menlo Park, CA 94025 NCPDP: 0553304
Safeway 0970 1655 El Camino Real San Mateo, CA 94403 NCPDP: 0587090

ATTACHMENT C TO EXHIBIT A
COMPENSATION FOR SERVICES – PHARMACY'S DISPENSING FEE

1. Pharmacy's Dispensing Fee for Pharmacy Services shall be as follows:

    a. For each prescription dispensed to eligible patients during the term of this Agreement under the San Mateo County Access to Care for Everyone (ACE) Program, San Mateo County ACE-County (formerly WELL) Program, San Mateo County Medicaid Coverage Expansion (MCE) Program, or County discount (cash) plan:

    $11.25 for each Brand Name Drug dispensed and $11.25 for each multi-source or generic drug dispensed.

    b. For Eligible Patients with third-party prescription insurance coverage (but excluding patients with Medi-Cal, who are not Eligible Patients):

    $20.00 for each Brand Name Drug dispensed and $20.00 for each multi-source or generic drug dispensed.

2. It is understood and agreed that: (i) Pharmacy shall receive the applicable Dispensing Fee for Pharmacy Services as set forth in this Attachment C for each successfully adjudicated claim (also referred to in this Agreement as a "Paid" response), (ii) Sentrex will re-examine all claims that have been processed for the previous invoicing period (if additional eligibility information has become available to make a previous ineligible claim now 340B eligible, Sentrex will add the additional 340B eligible claims from previous invoicing period to the current), and (iii) no retrospective denial or reversal is permitted except in the case of material error or payments inconsistent with usual and customary practices.

3. No additional fees shall be paid by County/Covered Entity for services under this Agreement.

4. All fees due under this Agreement are subject to the not-to-exceed amount listed in Section 3 of the Agreement.

ATTACHMENT D TO EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program—Contract

Pharmacy Services AGENCY: Health Resources and Services

Administration, HHS.

ACTION:
Final notice.

SUMMARY: Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992" enacted Section 340B of the Public Health Service Act (PHS). Section 340B implements a drug pricing program by which manufacturers who sell covered outpatient drugs to particular covered entities listed in the statute must agree to charge a price that will not exceed the amount determined under a statutory formula. The purpose of this Final Notice is to inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies and suggested contract pharmacy provisions, which had been previously limited to the Alternative Methods Demonstration Project program.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, Maryland 20857 or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

DATES: *Effective Date:*
April 5, 2010.

SUPPLEMENTARY INFORMATION:

A. Background

Proposed guidelines for contract pharmacy services were announced in the **Federal Register** at 72 FR 1540 on January 12, 2007. A comment period of 60 days was established to allow interested parties to submit comments. HRSA, HSB, acting through the OPA, received 32 comments concerning the proposal.

In 1996, HRSA issued guidelines that permitted covered entities participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the

covered entity's patients (61 FR 43549, August 23, 1996). Those guidelines permitted a covered entity to use a single point for pharmacy services, either an in-house pharmacy or an individual contract pharmacy. Since 2001, covered entities that have wanted to use other types of arrangements, or to blend the method of providing services (*e.g.* contract pharmacy to supplement an in- house pharmacy) have needed to apply to the OPA for an Alternative Methods Demonstration Project (AMDP) and secure approval in order to proceed.

It is important for all covered entities to keep in mind that use of a contract pharmacy arrangement (single, multiple or AMDP) does not lessen a covered entity's duty to ensure that the 340B program is being administered in compliance with the statute and HRSA guidelines. The covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a drug is subject to both the 340B discount and a Medicaid Rebate claim. Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition. Auditable records must be maintained to demonstrate compliance with those requirements. Such records must be maintained for as long as required by Federal, State and local law. Additionally, compliance with 340B requirements and guidelines does not excuse individual providers, covered entities, pharmacies, wholesale distributors or manufacturers from adherence to all

other local, State or Federal
requirements.

Covered entities should also be mindful that use of a contract pharmacy is voluntary. Covered entities are not required to use multiple contract pharmacies or any contract pharmacy at all. Each covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services.

We received many comments in support of the proposal. Many of these came from covered entities that participate in 340B and highlighted how their delivery of patient care would be enhanced with a multiple contract pharmacy option. According to these comments, some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities. This would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served.

Comments raised a number of issues: Audits; protecting against diversion; network models; limits on the number or location of contract pharmacies; and the

need for model agreement provisions and certification procedures. Also addressed was the potential impact on manufacturers, pharmacies, covered entities and patients. Additional comments challenged the sufficiency of the data used to justify the changes, and questioned whether the proposed notice was in compliance with the Administrative Procedure Act.

The following section presents a summary of all major comments, grouped by subject, and a response to each grouping. All comments were considered in developing this Final Notice, and changes were made accordingly. Other changes were made to improve clarity and readability.

B. Comments and Responses

(1) Administrative Procedure Act (APA) Compliance

Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.

Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA. Nonetheless, HRSA has published these guidelines in the **Federal Register** and provided a public comment period to obtain input into guideline development. The present guidelines used this same process. HRSA has considered all comments, both Federal and public, in developing the Final Guidelines.

Comment: Eleven demonstration projects out of a total of 12,000 covered entities do not give HRSA enough data to expand the scope of the contract pharmacy model. An additional demonstration project, with not less than 100 sites, should be the next step to further evaluate risks and benefits of the expanded model.

Response: At the time of publication of the proposed guidance there had been 18 demonstration projects. HRSA realizes that only a small percentage of covered entities have gone through the AMDP process. HRSA is working with the data that exists, which was overwhelmingly supportive of the guidelines. Although there have been a limited number of AMDPs approved, some of the approved projects included a large number of health care sites and contract pharmacies. The number of participating health care sites exceeded 50 and the number of contract pharmacy sites was over 170. The results of the AMDP are not the only basis for issuing this guidance. The circumstances surrounding pharmacy practice and the resources available to track transactions have changed substantially over the past decade.

The AMDP provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity. Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site. The restriction has imposed its own costs by restricting the flexibility of covered entities in meeting the needs of their patients. Furthermore, pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion. The use of multiple contract pharmacies is not appropriate for all covered entities; however, we do not find a blanket restriction on all covered entities to be justified.

Many commenters presented varying perspectives on the topic of audits. Multiple comments from drug manufacturers argued that manufacturers should be given the ability to audit covered entities that use multiple pharmacy contracting services due to the heightened risk of drug diversion and duplicate discounts. Other comments focused on HRSA audit requirements, arguing that they should be identical to the current standards required for the AMDP. Finally, some comments supported not having an audit requirement, arguing that audits would be burdensome and costly for the covered entities.

Comment: The audit requirements from the AMDP process should be applied to multiple contract pharmacies. There is no evidence of diversion and duplicate discounts because of the audit requirements. Their elimination may lead to increased diversion and duplicate discounts. Some commenters recommended retaining the audit requirements for at least a few years until a track record of compliance with multiple contract pharmacies can be created. Audits should include a full compliance review of all mandatory contract terms/ requirements including implementation of tracking system, patient status verification, and providing information about other pharmacy options.

Response: Although HRSA does not believe that precisely the same procedures are appropriate as utilized under the AMDP, HRSA agrees that independent audits can play an important role in ensuring program integrity. The guidelines have been revised to state that the covered entity must have sufficient information to meet its obligation of ensuring ongoing compliance and the recognition of any problem. Furthermore, the guidelines have been revised to indicate that it is the expectation of HRSA that covered entities will fulfill their ongoing obligation by the utilization of independent audits. However, HRSA leaves it up to covered entities to determine how to meet their compliance responsibilities. The guidelines intentionally do not specify the precise method, personnel or items for ensuring sufficient information is obtained by the covered entity. As long as covered entities comply with their obligations under the guidelines, HRSA prefers to leave the method of compliance to the judgment of the covered entities.

To the extent that any internal compliance activity or audit performed by a covered entity indicates that there has been a violation of 340B program requirements, it is HRSA's expectation that such finding be disclosed to HRSA along with the covered entity's plan to address the violation.

Comment: A copy of the audits conducted by covered entities should be submitted to OPA. The results of such audit should be made available to manufacturers.

Response: HRSA does not feel there is a need for the automatic submission of audits conducted by covered entities. HRSA believes that there are already appropriate safeguards in place. Covered entities are required to maintain auditable records sufficient to demonstrate continued compliance with 340B requirements; and, to the extent that a situation warrants, HRSA will request copies of any internal compliance documents of covered entities.

Comment: Covered entities should be required to conduct audits of their contract pharmacies and be required to terminate the contract with pharmacies found to be in violation.

Response: As noted earlier, HRSA agrees that audits can play an important role in ensuring integrity, and that covered entities are required to have sufficient information to ensure against diversion and duplicate discounts. The extent to which an audit of the contract pharmacy or other arrangement is necessary to satisfy that obligation will depend upon the individual circumstances. Covered entities have the responsibility to have agreements with contract pharmacies and procedures in place sufficient to enable the covered entity to meet its obligations under the law, including the prohibition on diversion and duplicate discounts. While an audit capability and various grounds for termination are terms that could be included in such contracts, there is no requirement in the guidelines for such terms. However, covered entities are reminded that they retain ultimate responsibility for compliance with the 340B program. Covered entities may be well-served by ensuring that compliance terms are included in their pharmacy contracts. To the extent that covered entities uncover these problems, the appropriate response is to report those problems to HRSA and ensure that they are properly addressed.

Comment: Manufacturers should be permitted to audit covered entities that use multiple contract pharmacy services. No reasonable cause should be required, due to heightened risk of diversion.

Response: We do not agree that utilization of more than one contract pharmacy creates automatic cause to suspect diversion. The issue as to whether additional audits by an outside manufacturer are permitted is addressed in the guidance published in the **Federal Register** on that issue (61 FR 65406, December 12, 1996). To the extent a manufacturer believes there is a reasonable basis to conclude that a covered entity is in breach of program requirements, it may audit a covered entity

consistent with these guidelines. Additionally, HRSA has developed a dispute resolution process to provide parties with an informal mechanism to bring before the Department allegations of behavior that are in violation of 340B. For further guidance on the audit and dispute resolution process *see* 61 FR 65406 (December 12, 1996). As indicated in this guidance, covered entities and contract pharmacies must retain auditable records of 340B covered drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non-patients and against duplicate discounts.

Comment: It would be burdensome for covered entities to provide reports and data for audits. It is unclear who would be required to construct the actual components of the audit, what would be included, and who would pay for it.

Response: HRSA would like to remind all 340B stakeholders that it is an option for covered entities to voluntarily enter into contract pharmacy arrangements. Each covered entity is encouraged to conduct its own analysis of the costs and benefits of implementing or expanding their pharmacy services. It is the responsibility of the covered entity to ensure against diversion and duplicate discounts. Covered entities may determine how to best meet that responsibility: By performing a separate audit, including spot audits as part of pre-existing auditing responsibilities, or via other mechanisms. HRSA believes that including these issues as part of an independent audit is the best but not necessarily the only approach to meet covered entities' ongoing responsibility to know that their covered outpatient drugs are being appropriately ordered and distributed to their patients.

(2) Diversion

Comment: The proposed guidelines do not adequately describe safeguards that will combat drug diversion and duplicate discounts. There should be more severe penalties for violations, especially duplicate discounts. Reimbursement of any inappropriate discounts is insufficient and will not deter bad behavior. A covered entity should be excluded from 340B if it continues to use a pharmacy found to be in violation of the program.

Response: HRSA believes that there are appropriate safeguards in place, based on the parameters of the program. HRSA has the ability to exclude covered entities that abuse the program. HRSA has no statutory authority to assess additional penalties beyond the authority provided in section 340B. However, to the extent HRSA is aware that an action by a covered entity or contract pharmacy may be a violation of the law, such cases are referred to appropriate authorities.

Comment: The proposed guidance appears to limit the need to segregate records for easy accessibility by auditors rather than for purposes related to ensuring there is no diversion. Is this intended, or is segregation, virtual or otherwise, still expected

to be used by the contract pharmacy as a method of showing that diversion has not occurred?

Response: All covered entities are required to have auditable records sufficient to fully demonstrate compliance with all 340B requirements. Any covered entity that chooses to utilize a contract pharmacy must ensure that any such contract fully addresses that requirement and has the responsibility to ensure that the contract is actually performed and administered in compliance with those requirements. Inventory and record segregation is one of many methods that can be used to ensure compliance with the program guidelines. HRSA does not intend to limit the methods covered entities may use in order to remain in compliance with the guidelines. As noted previously, covered entities and contract pharmacies must retain auditable records of 340B covered drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non- patients as well as duplicate discounts.

Comment: Covered entities should be required to maintain and provide to HRSA and manufacturers written policies and procedures for preventing diversion and duplicate discounts in their contract pharmacy services.

Response: The ultimate responsibility for compliance with all aspects of the 340B program lies with each covered entity. The contract arrangements between covered entities and outside pharmacies will have various terms and procedures, which are acceptable as long as there are no violations of the program. It is expected that all covered entities will have written policies and procedures for preventing diversion and duplicate discounts as part of their obligations to prevent diversion and duplicate discounts. They are also required to maintain auditable records. HRSA will not automatically require covered entities to submit such policies and procedures for HRSA review.

(4) Contract Pharmacy Services Mechanism—Potential Alternatives to Single Location/Single Pharmacy Model Comment: HRSA should permit separate covered entity sites to enter into one comprehensive agreement between the sites and a single contract pharmacy, instead of requiring a separate agreement for each site. Additionally, HRSA should permit a covered entity to enter into one comprehensive agreement with a chain pharmacy binding on multiple locations of the chain, instead of requiring a separate agreement for each contract pharmacy site.

Response: Each covered entity retains its own responsibility for compliance with the program. With respect to a covered entity with multiple sites, HRSA agrees that a single covered entity may contract for sites that are integral parts of the covered entity and for which it has legal control of so long as all of the requirements are met in the contract. This approach maintains and recognizes the central responsibility of the covered entity. In the case of agreements with "chain pharmacies," there appears to be potential for loss of accountability without a clearly established relationship between the actual pharmacy site and the covered entity. Covered entities are not precluded from entering into agreements with chain pharmacies, however, each

participating pharmacy location must be listed on the contract and comply with the requirements.

Comment: One comment suggested that HRSA should clarify the definition of "multiple." The commenter interprets "multiple" to mean that an FQHC could contract with more than one pharmacy, including more than one site of a chain pharmacy, more than one independent pharmacy, or a combination of chain sites and independent pharmacies. Additionally, the commenter interprets "multiple" to mean that a covered entity with an in-house pharmacy could use any acceptable contract pharmacy arrangement to supplement the in-house pharmacy. The commenter encourages OPA to adopt this interpretation in the final guidance.

Response: HRSA agrees with the comment about the meaning of "multiple" and believes that the Final Notice
is clear with respect to
this meaning.

Comment: Does a covered entity that currently has an agreement with only one contract pharmacy need to revise its agreement with that pharmacy if the entity subsequently enters into agreements with additional pharmacies?

Response: The covered entity may need to revise its existing contract, depending on the terms that it contains. There is no requirement in the guidelines to revise contracts, as long as they meet the criteria outlined. All entities are encouraged to seek competent counsel to assess their needs.

Comment: The proposed guidelines do not provide cautionary language about possible negative results of implementing a multiple contract pharmacy model. Some small pharmacies that currently contract with covered entities may be hurt by implementation of the guidance due to reduced business. More guidance and decision analysis tools should be provided to guide the process of deciding whether to implement.

Response: HRSA notes that participation in any multiple contract pharmacy models is completely voluntary. All stakeholders are encouraged to conduct a full business analysis to determine whether to implement a multiple contract pharmacy model before moving forward. HRSA also provides free technical assistance for covered entities, including assistance with business analysis, to help navigate these issues. Ultimately, the decisions and responsibility for those decisions lies with the covered entity.

(5) Network Models

Comment: Multiple commenters proposed that network arrangements (*i.e.* arrangements involving a network of more than one covered entity) should be permitted under the guidelines without prior approval from HRSA. They argued that

network arrangements would decrease the burden on covered entities and contract pharmacies by simplifying the contracting process and maintaining multiple inventory records. They also made the point that networks would also encourage parties to participate in 340B and therefore, expand access to eligible patients.

Response: HRSA understands the comments that a network model might potentially ease the administrative burden for participants in some cases. However, due to ongoing concerns about maintaining the integrity of the program with such complex arrangements, at this time, we decline to include network models in the guidelines without the added scrutiny of the AMDP process. HRSA will reassess the appropriateness of the utilization of networks outside the AMDP process as sufficient experience with them is gained in the future.

Comment: Some comments urged HRSA not to permit networks of multiple covered entities outside the framework of the AMDP process and requested confirmation that under the new guidance the development of a network of 340B covered entities will remain subject to the entire process now applicable to the AMDPs.

Response: HRSA agrees that covered entity networks should remain under the AMDP process, as indicated in the response to the prior comment.

Comment: "All covered entities participating" language is unclear. Does it mean a covered entity with multiple sites, a network model, or a Covered Entity would need to name each covered entity that has an agreement with a pharmacy under contract with the covered entity? If so, that would be burdensome on the entity, which would need to research and identify other covered entities that may contract with a particular pharmacy. What is the justification for requiring a covered entity to specify the names and 340B ID numbers of other participating covered entities?

Response: If a covered entity wants to use any alternative to a single location/ single pharmacy model, it must submit its name and 340B identification number, and the names of all participating pharmacies to HRSA. Network models will still need to go through the AMDP process. The commenter is correct that the "all covered entities participating" language is unclear, because such arrangements only apply to a single covered entity. The language has been changed in response to this comment.

Comment: The guidelines should limit the numbers and geographical locations (not over State lines) for contract pharmacy relationships. Perhaps contract pharmacies should only be added one at a time. Monitoring various sites by the covered entity may be extremely difficult unless safeguards are in place.

Response: HRSA understands the commenter's concerns, but at this point, HRSA declines to limit the number of arrangements, as long as each arrangement meets our guidelines. Each covered entity retains the obligation to ensure its program remains compliant with the guidelines. HRSA does not intend to prescribe the methods covered entities use to run their programs or to ensure compliance at this time. Each

covered entity and contract pharmacy is responsible for ensuring that its particular contracting arrangements and operations conform to the requirements of all applicable Federal, State and local laws and regulations.

(6) Model Agreement Provisions/ Covered Entity Compliance Elements

In the final guidelines the phrase "Model Agreement Provisions" has been changed to "Covered Entity Compliance Elements" to better reflect the purpose of the elements and to distinguish them from model contract provisions.

Comment: Covered entities with multiple contract pharmacy arrangements should have written contracts with each pharmacy, including procedures to ensure against drug diversion and duplicate discounts, to maintain records available for audit, and to meet all other 340B requirements. Covered entities should submit these contracts and procedures to HRSA.

Response: HRSA agrees in part, which is why the guidelines do require a covered entity to have a contract that specifies all participating pharmacy locations. Such contracts must include adequate terms to ensure compliance with all aspects of the 340B program as listed in the Covered Entity Compliance Elements. However, at this time, HRSA does not have the need, or the resources to collect and review each contract. The covered entity bears responsibility for compliance with the program and will be held accountable in the event of non- compliance.

Comment: HRSA should create a single list of model contract terms, add suggested language on duplicate discount prohibition, and require covered entities to certify that their contracts use these terms or apply to HRSA for approval to use alternative terms.

Response: The Appendix of the guidelines does include a list of suggested contract provisions. HRSA has included provisions necessary to ensure that covered entities and contract pharmacies understand and agree not to violate 340B provisions. Because of the wide diversity of covered entities, it would be impossible to include provisions that would respond to the needs of all covered entities.

Comment: Manufacturers should be allowed to request copies of the contracts between the covered entities and contract pharmacies.

Response: Manufacturers are certainly permitted to request copies of such contracts, however, HRSA declines to mandate that covered entities must provide copies of contracts upon any request. In the event a manufacturer demonstrates a reasonable need for the copy of a contract and its request for a copy of the contract has been denied, the manufacturer may ask OPA to obtain a copy. The suggested Covered Entity Compliance Elements include providing a copy of the contract pharmacy service agreement upon the request of the Office of Pharmacy Affairs.

Comment: The Appendix provisions impose additional requirements not discussed in Section (3) of the proposed guidance and the suggested provisions in Section (3) do not appear in the Appendix. The Appendix does not mention the 340B prohibition on duplicate discounts.

Response: The Suggested Contract Provisions, found in the Appendix of the Guidelines, are not meant to be comprehensive, exhaustive, or required. They offer a model format and sample provisions, but are not intended to be used as the complete terms of the contract.

Comment: Covered entities should not be permitted to use alternative mechanisms other than the model agreement provisions. The use of alternatives would increase OPA's oversight responsibilities, which may lead to different standards or the potential for abuse. A commenter also cited GAO/OIG reports on lack of oversight of the program to support his/ her assertion that the model provisions should be required.

Response: The Covered Entity Compliance Elements are not intended to be required contract provisions. All covered entities must certify that all of the elements have been addressed; however, HRSA gives the covered entities the discretion to negotiate contract provisions suitable to their individual circumstances and jurisdictions. The various complexities of covered entities and the pharmacies with whom they will contract led HRSA to permit flexibility between the parties in designing their contract terms. HRSA does not intend to review contracts. As under the previous guidelines, the covered entity is ultimately responsible for assuring full compliance with 340B. HRSA disagrees with the comment that recent reports by the GAO and the OIG would support the creation of a standard uniform contract. HRSA has worked diligently to implement the recommendations of both the GAO and the OIG, and HRSA does not believe that dictating to covered entities specific contract language that must be used in all contracts regardless of individual circumstances would assist in those efforts at this time.

(7) Miscellaneous Comments

Comment: Anti-kickback provisions may prohibit pharmacies from offering Medication Therapy Management and Pharmacy by Mail activities that would be beneficial to 340B and patients.

Response: Covered entities are not exempt from anti-kickback provisions. Section 340B does not authorize HRSA to grant any exceptions whether beneficial or not. It is recommended that covered entities get competent professional legal advice when appropriate.

Comment: In section B(3)(c), the proposal states that the manufacturer is not required to offer the 340B drug price if the patient declines to use the contract

pharmacy. If however, the manufacturer does extend the 340B price in this case, please clarify whether this extension sets a new best price for the drug.

Response: The 340B drug pricing program does not restrict the prices that manufacturers voluntarily choose to offer to patients outside the parameters of the program. Whether such actions serve to set a new best price for a drug is beyond the scope of this guidance. We encourage anyone with specific best price questions to consult with the Centers for Medicare & Medicaid Services.

Comment: To prevent drug diversion, an additional contract requirement should be added that the contract pharmacy may not fill or refill a prescription using 340B medications until the covered entity confirms that the individual is a patient of the entity at the time the prescription is filled. There should also be an independent, annual audit to review the covered entity's policies and procedures for patient verification.

Response: The program guidelines for 340B make it clear that only individuals who are patients of the covered entity are eligible for drugs purchased under the program. Like all other program requirements, responsibility for compliance lies with the covered entity, which must structure agreements and systems appropriately to ensure that diversion does not occur. Technical assistance may be available for help with implementation and compliance for the 340B program, and maximizing the value of comprehensive pharmacy services for their patients. However, HRSA has chosen not to require time-of- services verification as suggested in the comment.

Comment: Pharmacy records from contract pharmacies should be made available to covered entities to ensure patient safety and continuity of care.

Response: HRSA agrees that this might be beneficial for patient care and encourages the parties to include such terms in their contract agreements. However, this is a decision which will be left to the contracting parties. In any case, the covered entity must have sufficient records or direct access to records for the covered entity to meet its responsibility to ensure compliance and to provide a complete audit trail to verify that there is no diversion or duplicate discounts.

Comment: HRSA should include in its final guidance and suggested contract provisions, language to reinforce that all savings from the 340B program should remain with the covered entity. Without written guidance, all savings will not be returned to the covered entity.

Response: HRSA agrees that the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the program was intended to accrue to the covered entities. However, the covered entity is free to negotiate how it chooses to use any such funds as it sees fit. For example, the covered entity is free to choose to use those dollars to pay contract pharmacies for their services or for extra services such as delivery.

C. Contract Pharmacy Services Mechanism

These final guidelines replace all previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the "Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services," (61 FR 43549) and any individual correspondence issued by HRSA on the subject.

(1) Basic Compliance Issues in Utilization of Pharmacy Services Contracts

A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy. A single covered entity that has more than one 340B eligible site at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate "in-house" pharmacy services, those covered entities that have access to "in-house" pharmacy services but wish to supplement these services; and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The covered entity has the responsibility to: Ensure against illegal diversion and duplicate discounts; maintain readily auditable records; and meet all other 340B Drug Pricing Program requirements (*See: http:// www.hrsa.gov/opa/introduction.htm*). HRSA has provided essential covered entity compliance elements below as guidance for the type of contractual provisions expected in such agreements. Suggested contract provisions are also in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (5) below.

(2) Potential Alternatives to Single Location/Single Pharmacy Model

In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies only if: (a) There is a written agreement and procedures that meet the requirements outlined above in (1) between the covered entity and each pharmacy; (b) the written agreement includes, and fully addresses, all of the essential elements outlined in (3) and (4) below and a full listing of all pharmacy locations that may be utilized under that agreement; (c) the operation under the contract continues to meet all 340B Drug Pricing Program requirements and does not create diversion of covered drugs or duplicate discounts; (d) the arrangements are one of the two following models either individually or in combination: (i) The use of multiple contract pharmacy service sites, and/or (ii) the utilization of a contract pharmacy(ies) to supplement in-house pharmacy services (the use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B

discounted prices for its patients at more than one pharmacy location). Supplementing in- house pharmacy services with a contract pharmacy refers to any arrangement wherein a covered entity site purchases drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location; and (e) the arrangement involves a single identifiable 340B covered entity and does not include a network, or other similar arrangement, of more than one covered entity unless specifically authorized in writing by HRSA through an AMDP or by other official written authorization.

(3) Essential Covered Entity Compliance Elements

The following are essential elements to address in contract pharmacy arrangements:
(a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State and local laws.

A "ship to, bill to" procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. *See* Section 1 of Appendix. In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (*e.g.,* dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services). Each covered entity has the option of individually contracting for pharmacy services with a pharmacy (ies) of its choice. Covered entities are not limited to providing comprehensive pharmacy services to any particular location and may choose to provide them at multiple locations and/or "in-house."

(c) The covered entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a pharmacy other than a covered entity's contract pharmacy or the covered entity's in-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity (*e.g.,* home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (*e.g.,* quarterly billing statements, status reports of collections and receiving and dispensing records). *See* Section 2 of Appendix.

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. *See* Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. The system should be subject to modification in the event of change in such guidelines.

Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. See 42 U.S.C. 256b(a)(5)(B). The covered entity understands that it may be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing. *See* Section 4 of Appendix.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA, HRSA, by the covered entity.

(j) The covered entity and contract pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.

(k) Both parties understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. *See* 42 U.S.C. 256b(a)(5)(c).

The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.

(I) Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

(4) Ongoing Responsibility of Covered Entity To Ensure Compliance

Covered entities are responsible for ensuring that the system of distribution chosen fully meets statutory obligations of ensuring against diversion to non-patients or creating a situation that results in a State Medicaid Program seeking a rebate on a discounted drug. The covered entity remains responsible at all times for the disposition of covered outpatient drugs it purchases through a contract pharmacy. Annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected, although the exact method of ensuring compliance is left up to the covered entity. The covered entity must have sufficient information to ensure it is meeting that responsibility. Independent audits are particularly valuable where the covered entity utilizes multiple pharmacy options. They should follow standard business practices for audits, including audit trails provided by the entity to the auditor, and use of standard reports. The precise methodology utilized to ensure compliance and obtain the necessary information is up to the covered entity given its particular circumstances and, for example, might include spot audits where the system in place permits. Drug diversion and duplicate discounts are a significant concern of HRSA and all efforts to avoid these problems should be well documented. In the event a covered entity determines that drug diversion or duplicate discounts have occurred or that it is otherwise unable to comply with its responsibility to reasonably ensure compliance, then it must take immediate remedial action to assure compliance and notify the OPA about such compliance problems and actions taken to remedy those problems.

(5) Certification

Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. If the covered entity directs the drug shipment to its contract pharmacy or pharmacies, the covered entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide HRSA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, covered entities should

submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy or pharmacies that satisfies both (3) and (4) above (*i.e.* that the contract(s) fully address the issues listed in (3) and that the covered entity has a plan to meet its ongoing responsibilities to ensure compliance). The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing and the names of any pharmacies participating when registering. Covered entities seeking to materially change this arrangement that entail changes in the covered entity database should notify OPA of any such proposed changes and be aware that some changes may require advanced notice to manufacturers and wholesalers as part of quarterly updates to the database.

In order to ensure accuracy, integrity and transparency, the OPA may conduct a recertification process periodically (most likely annually) where covered entities affirmatively certify as to their ongoing compliance with 340B requirements. It is currently expected that the annual process would include certification by a duly authorized official: (1) That all information listed on the database for that covered entity is complete, accurate, and correct; (2) that the covered entity met the 340B eligibility requirements throughout the prior year and continues to do so; (3) that any contract pharmacy arrangement was actually performed in accordance with specified requirements including, but not limited to, that the covered entity obtained sufficient information from the contractor to ensure compliance with applicable policy and legal requirements; and (4) the methodology utilized to ensure compliance (*e.g.* through independent audit or other mechanism).

(6) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b).

D. Appendix—Suggested Contract Provisions

The following suggested contract provisions are included for illustrative purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for consideration, but are not intended to be used as the complete terms of the contract. Given the variances among many jurisdictions and among the

numerous types of covered entities, HRSA has decided at this time not to include a complete model contract in this notice.

(1) "The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the pharmacy."

(2) "The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: Prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations."

(3) "Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity."

(4) "The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care prescribers and will update the list of prescribers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer."

Dated: March 2, 2010. Mary K. Wakefield, Administrator.
[FR Doc. 2010–4755 Filed 3–4–10; 8:45 am]
BILLING CODE 4165–15–P

Expiration Date: 8/31/2012 Revised March 2010

EXHIBIT E

CORPORATE COMPLIANCE SMMC CODE OF CONDUCT (THIRD PARTIES)

The person/entity listed below (the "Undersigned") recognizes and is fully dedicated to advancing SMMC's commitment to full compliance with all Federal, State, and other governmental health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements.

The Undersigned will comply with all Federal, State or other governmental health care program requirements and with SMMC's policies and procedures relating to SMMC's Corporate Compliance Program, including the requirements set forth in the Corporate Integrity Agreement (CIA) to which SMMC is a party (available online at http:// oig.hhs.gov/fraud/cia/agreements/the_county_of_san_mateo_03062009.pdf).

The Undersigned, to the extent its contractual duties require it to submit the reports covered in this paragraph, will promptly submit accurate information for Federal health care cost reports including, but not limited to, the requirement to submit accurate information regarding acute available bed count for Disproportionate Share Hospital (DSH) payment.

The Undersigned will report to the SMMC Compliance Officer any suspected violation of any Federal health care program requirements or of SMMC's Compliance Program policies and procedures.

The Undersigned has the right to use the SMMC Disclosure Program by calling the Compliance Hotline or reporting incidents to the Compliance Officer. SMMC is committed to non-retaliation and will maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

The Undersigned understands that non-compliance with Federal health care program requirements and SMMC's Compliance Program policies and procedures, and failing to report such violations, could result in termination of the Agreement and/or any other penalties permitted by law.

The Undersigned is responsible for acquiring sufficient knowledge to recognize potential compliance issues applicable to the duties outlined in the Agreement and for appropriately seeking advice regarding such issues.

The Undersigned will not offer, give or accept any bribe, payment, gift, or thing of value to any person or entity with whom SMMC has or is seeking any business or regulatory relationship in relation to said business or regulatory relationship (other than payments authorized by law under such relationships). The Undersigned will promptly report the offering or receipt of such gifts to the SMMC Compliance Officer.

The Undersigned will not engage in any financial, business, or other activity which competes with SMMC/County business which may interfere or appear to interfere with the performance of the duties under the Agreement or that involve the use of SMMC/County property, facilities, or resources, except to the extent consistent with the SMMC/County Incompatible Activities and Outside Employment policy and the Agreement.

The Undersigned will cooperate fully and honestly with internal audits and monitoring programs to help assure that SMMC's compliance is maintained with all applicable federal/state regulations, the Joint Commission standards, and hospital system-wide policies.

TO REPORT VIOLATIONS, CALL THE COMPLIANCE HOT LINE: (800) 965-9775

The Undersigned hereby certifies by signing below that an authorized representative has received this Code of Conduct, understands it, has authority to commit the Undersigned to this Code of Conduct, and hereby commits the Undersigned to comply with this Code of Conduct.

Mark Tamll

Name of Person/Entity (the "Undersigned")

Signature and Printed Name

5/30/2013

Date

ATTACHMENT I

Assurance of Compliance with Section 504 of the Rehabilitation Act of 1973, as Amended

The undersigned (hereinafter called the "Contractor(s)") hereby agrees that it will comply with Section 504 of the Rehabilitation Act of 1973, as amended, all requirements imposed by the applicable DHHS regulation, and all guidelines and interpretations issued pursuant thereto.

The Contractor(s) gives/give this assurance in consideration of for the purpose of obtaining contracts after the date of this assurance. The Contractor(s) recognizes/recognize and agrees/agree that contracts will be extended in reliance on the representations and agreements made in this assurance. This assurance is binding on the Contractor(s), its successors, transferees, and assignees, and the person or persons whose signatures appear below are authorized to sign this assurance on behalf of the Contractor(s).

The Contractor(s): (Check a or b)

☐ a. Employs fewer than 15 persons.

☐ b. Employs 15 or more persons and, pursuant to section 84.7 (a) of the regulation (45 C.F.R. 84.7 (a), has designated the following person(s) to coordinate its efforts to comply with the DHHS regulation.

_____
Name of 504 Person - Type or Print

Safeway Inc.
Name of Contractor(s) - Type or Print

20427 N 27th Ave
Street Address or P.O. Box

Phoenix, AZ 85027
City, State, Zip Code

I certify that the above information is complete and correct to the best of my knowledge.

_____
Signature

Director
Title of Authorized Official

5/30/2013
Date

*Exception: DHHS regulations state that:

"If a recipient with fewer than 15 employees finds that, after consultation with a disabled person seeking its services, there is no method of complying with (the facility accessibility regulations) other than making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the handicapped person to other providers of those services that are accessible."