

**SECOND AMENDMENT TO AGREEMENT  
BETWEEN THE COUNTY OF SAN MATEO AND  
DIAMOND PHARMACY SERVICES**

THIS AMENDMENT TO THE AGREEMENT, entered into this \_\_\_\_ day of \_\_\_\_\_, 2010, by and between the COUNTY OF SAN MATEO, hereinafter called "County," and DIAMOND PHARMACY SERVICES, 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/Agency thereof;

WHEREAS, it is necessary and desirable that Contractor be retained for the purpose of performing the professional services for the Health System, Correctional Health Division; and

WHEREAS, the parties entered into an Agreement for pharmaceutical services on July 1, 2005; and

WHEREAS, the parties amended that Agreement on May 20, 2008; and

WHEREAS, the parties wish to further amend the Agreement to allow for Contractor to provide Correctional Health Services with 340B Covered Prescription Drugs.

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

Original Exhibit A is replaced with Revised Exhibit A to read as follows:

Exhibit "A"

**Definitions.**

- a. "340B Drugs" are hereby defined in accordance with applicable laws and guidance at 42 U.S.C. § 256b(b), 42 U.S.C. § 1396r-8(k), and 59 Fed. Reg. 25,110 (May 13, 1994).
- b. "Tracking System" is hereby defined as a system for identifying and monitoring the use of drugs through all phases of the Parties' involvement

with such drugs, including the ordering of 340B drugs, the receipt of 340B drugs, Covered Entity's payment for 340B drugs, internal transfers of 340B drugs within the Pharmacy, Contractor's preparation and dispensing of 340B drugs, and Contractor's billing of the Covered Entity Patient or third-party insurer for the 340B drugs on behalf of Covered Entity.

- c. "Pharmacy" shall mean the legal entity identified in this Agreement. If there is more than one Pharmacy location that shall be utilized by Covered Entity in order to serve Covered Entity patients, each Pharmacy site shall be identified.
- d. "Covered Entity" shall mean the legal entity identified in this Agreement, including all of its 340B-eligible clinical site locations. San Mateo Medical Center is legal entity identified as the covered entity.

## RECITALS

A. The 1992 Veteran's Health Care Act created Section 340B of the Public Health Services Act, which classifies certain health care clinics, including the Correctional Health Services ("County"), as "**Covered Entities**" eligible to purchase outpatient prescription drugs for their patients at favorable discounts from drug manufacturers who enter into drug purchasing agreements with the United States Department of Health and Human Services ("**DHHS**").

B. California Business & Professions Code §4126, effective January 1, 2002, authorizes Covered Entities, including County, to contract with pharmacies licensed under California state law, such as Contractor, to dispense Covered 340B Drugs for the Covered Entity, provided certain requirements are met, including adequate inventory control and limitation of dispensing to eligible outpatients of the Covered Entity.

C. The County of San Mateo, Correctional Health Services and Contractor mutually desire to enter into a "ship to/bill to" arrangement under which Contractor will order Covered 340B Drugs and receive shipment, maintain inventory and controls, dispense such drugs on behalf of County only to eligible outpatients, and charge and collect for such drugs, all on County's behalf, and County will be billed and will pay for such drugs, in compliance with applicable laws and regulations.

D. County and Contractor mutually acknowledge that their intent in entering into this Agreement is solely to facilitate Correctional Health Services' participation in the 340B drug purchasing program, without having to establish and operate its own pharmacy. The services provided each to the other are only those necessary in order to fulfill this intent, and all financial arrangements established herein are mutually determined to represent either cost or fair market value for the items and services received. The parties expressly do not intend to take any action that would violate state or federal anti-kickback prohibitions, such as those appearing in Section 1128B of the Social Security Act, 42 USC Section 1320a-7b. Instead, it is the intention of the parties that this Agreement and all actions taken in connection herewith shall fully comply with

the regulatory requirements of the safe harbor for personal services and management contracts appearing in 42 CFR Section 1001.952(d), and this Agreement shall in all respects be construed consistent therewith.

NOW, THEREFORE, in consideration of the promises, covenants and agreements hereinafter set forth, County and Contractor hereby agree to the following terms and conditions:

In consideration of the payments set forth in Exhibit "B", Contractor shall provide the following services:

**A. PROVISION OF NON-340B PHARMACEUTICALS**

**1. Pharmaceuticals**

Contractor shall provide professional comprehensive pharmaceutical services for all prescription, non-prescription, and intravenous solutions as ordered by the physicians and the dentists including, but not limited to, medications for topical, oral, IV and injectable use, inhalers, suppositories, and ADAP medications: Generic substitutions will be provided when available and approved by the physicians. Only approved drugs, biologicals, and other related items will be sent to the facilities. All medications will be dispensed and labeled inmate/patient specific in complete compliance with all current and future local, state, and federal laws, regulations, provisions, and court orders. Prescriptions will be dispensed and sent in only the amount prescribed by the physicians.

**2. Supplies and Equipment**

Contractor shall provide medication cart(s), trays, storage supplies, dispensing equipment, packaging compartments, etc., for the efficient storage and administration of medication.

Contractor shall furnish a facsimile machine for the sole use of transmitting prescriptions and inmate/patient information to Contractor's pharmacy.

**3. Prescription Monitoring Services**

Prior to filling prescription orders, Contractor's clinical pharmacists shall screen each inmate/patient's complete computerized medication profile to ensure safe and therapeutic medication administration. Contractor shall screen for:

- duplicate therapy;
- drug interactions;
- excessive/sub-therapeutic dosages;
- a summary of all new and changed orders;
- inmate/patient drug allergies;
- medications which are being reordered too soon;
- medications ordered past the designated cut date; and
- overall prescription order accuracy.

Contractor shall alert County staff via phone or fax of such occurrences prior to shipping the order.

#### **4. Formulary Implementation and Management**

Contractor shall assist in the development, implementation, and compliance of a drug formulary for County. The purpose of the formulary is to utilize drugs within certain therapeutic classes based on therapeutic value and cost. Contractor shall utilize the existing County formulary and shall work in conjunction with the medical staff and the Pharmacy and Therapeutics Committee to discuss additions or deletions of medications by providing a monthly medication usage, cost comparisons and drug indication for particular drug classes. Contractor shall work along with the County medical staff using a team approach to drug therapy management at the most effective cost.

Contractor will require the use of non-formulary request forms for non-formulary medications, which will aid the doctors in utilizing only formulary items. Contractor will review non formulary medication usage at the facilities with physicians quarterly.

Physicians will be required to fill out a non formulary form prior to receiving a non-formulary prescription. If a non formulary medication is ordered without a form, Contractor will fax an alert to the physician requesting a non-formulary form to be completed or to change the order to a formulary medication. If a form is still not received, Contractor will send a limited supply of the order so the inmate/patient won't be without his medication.

Contractor will provide extensive formulary management services working in conjunction with the medical director and the physicians to reduce drug cost and to provide monthly usage data accompanied with graphs.

The formulary will be reviewed and updated on a quarterly basis.

#### **5. Dispensing Medications**

Ordering

County may place orders by phone or fax via Contractor's toll-free number.

Contractor will provide the following at no cost to County in order to expedite and assure accuracy of orders:

- a. Fax machine
- b. Daily drug order sheets necessary for transmitting new orders, reorders, changes, stop orders or discontinued orders
- c. Double peel-off labels for reordering
- d. Dedicated pharmacy technician designated to processing County's orders.

## 6. Delivery

All orders received by 2:00 PDT will be delivered next day air by 10:30 AM, six (6) days a week. Emergency deliveries will be provided twenty-four (24) hours a day, seven (7) days a week through emergency kit/starter packs or a pre-arranged contracted local back-up pharmacy at no additional fee.

Orders needed for emergency delivery will be phoned to Contractor twenty-four (24) hours a day, who will then coordinate the delivery with a pre-arranged contracted local back up pharmacy who will deliver the medication directly to the facility. The back up pharmacy will bill Contractor who will bill County, at the contracted rate.

Every medication shipment will contain detailed itemized packaging slips as a method of checking all items and cost accrued for each medication order/designated billing period. Reports can be sorted in any format and will include but are not limited to:

**Medication Delivery Report** - Printed alphabetically by inmate/patient containing inmate/patient name and number, date, medication name, strength, number of doses, prescription number and stop date.

**Scheduled Items Report** - Contains all above information exclusively printed for controlled substances.

**Billing Report** - Containing all above information in addition to drug NDC number and price.

**Tracking** - All next day air packages are tracked daily to ensure timely and accuracy of delivery.

## 7. Medication Distribution System

Contractor will provide and implement a specialized dispensing and delivery system in conjunction with the County staff which will meet County's needs for safe, efficient, accountable, feasible, and cost effective medication distribution. Prescription and non-prescription medications will be dispensed in your choice of unit-dose blister cards, conventional prescription vials, bulk or numerous other systems, as preferred. Medications will be dispensed to comply with County's self-medication program. Medications not intended for the self medication program can be marked with a fluorescent "no self med" sticker.

Controlled substances will be dispensed in a unique packaging which differs from other packaging.

## 8. Labeling

Each prescription will be labeled individually, with the inmate/patient's name and identification number, medication name and strength, generic interchange information, quantity dispensed, manufacturer's name, lot number, expiration date, route and times of administration, directions, inmate/patient location, prescription number, prescriber name, dispense date, cut date,

pharmacist's initials and refills (if any) in accordance with all federal, state and local laws and regulations.

Two (2) part peel-off reorder labels will be supplied for transmitting reorders to the Contractor.

Auxiliary labels will be placed on each prescription for safe and effective medication use describing reactions, cautions, warnings, interactions, etc. See below:

Starter Packs (on-site stat doses):

Starter packs of certain medications needed to begin therapy for immediate administration until an inmate/patient-specific prescription is received will be provided.

Medications and stock quantities for starter doses will be determined in conjunction with County.

Each starter pack will be accompanied by an accountability sheet for reconciliation of all doses.

The completed accountability sheet should be returned to the Contractor (for reconciliation of doses) when stock is depleted. The drug, however, may be reordered when needed by faxing the peel-off reorder label to the Contractor.

#### **9. Emergency Medication Kit**

The kit will contain only those medications which immediate administration is required in order to alleviate pain, infection, modify dangerous behavior, or to preserve a life.

Drugs and stock quantities will be determined in conjunction with County. All contents will be listed on the sealed kit. Contractor will inventory the kit quarterly, or as required by County. There will be no initial charge for items in the kit. Emergency medications not found in either the emergency medication kit or the starter packs will be delivered to County facilities by a back-up pharmacy.

#### **10. Monthly Supplies / House Stock**

Contractor will supply at County's request a complete line of over the counter medications (OTC's), health and beauty aids, durable medical equipment, medical supplies, enteral nutrition and respiratory therapy equipment. Contractor and County will determine a sufficient inventory stock amount. Appropriate stock quantity will be maintained by ordering in one (1) of three (3) ways:

A peel-off reorder label will be used on each stock item. When an item is used the label should be peeled off and faxed to Contractor on this appropriate order form.

Contractor will provide County with an order form of all stock items used. Each form would contain agreed minimum/maximum quantity needed on hand. When a minimum listed quantity

is reached enough should be ordered to achieve maximum listed quantity. This order form should be faxed to Contractor.

Reconciliation sheets showing declining stock inventory for each medication to account for all doses dispensed will be used. When inventory reaches an agreed minimum amount the form will be faxed to Contractor in order to achieve the agreed maximum amount.

**11. Efficiency**

Contractor will review County's facility set up, make recommendations and work cooperatively to establish the most cost effective and efficient system possible.

**12. Accountability**

Contractor will maintain all appropriate documentation including, but not limited to, inventory records, controlled drug perpetual inventory, patient profiles, copies of all prescriptions, etc. All documentation shall be open for review by the appropriate prison staff or appointed designee.

Contractor will provide and implement a record keeping system for drug accountability throughout the institution.

Contractor will maintain extensive patient profiles and provide accurate pre-printed MAR's once monthly for each inmate/patient receiving medication, if requested. MAR's can contain inmate/patient's name, allergies, diagnosis, physician's name and current medication list with directions. This serves as a charting mechanism for safe and efficient documentation of medication administration.

**13. Protocols, Policies and Procedures**

Contractor will assist in developing, implementing, updating, and monitoring of policies and procedures for safe and effective distribution, control, and use of drugs and supply County with policy and procedure manual. This manual will include policies on the AIDS Drug Assistance Program (ADAP) medications grant, IV services, self-medication program, etc. and will be updated quarterly.

**14. In-service Training and Continuing Education**

Contractor will provide customized inservice training on a variety of topics tailored to educate the staff to ensure compliance and enhance staff knowledge to better care for the inmates/patients. The inservices will include at a minimum: information regarding adverse drug reactions, drug interactions, basic review of formulary at facilities, new and/or revised laws pertaining to pharmacy, new medication, med pass, medication accountability.

Contractor will make available to County at no charge its health care video library on various medical-related topics.

Contractor will also supply County with a monthly newsletter highlighting new drug information, medical terminology review, metric equivalents, adverse drug reactions, research news on medications, news briefs on patient care, etc.

Contractor will also provide drug reference materials as needed such as controlled substance lists, list of medications that should not be crushed, metric conversions, poison antidotes, etc.

## **15. Utilization Data**

Documentation and Monthly Management Reports:

Contractor will provide any requested computer generated reports and utilization data. All reports can be sorted in any order or groupings including by prescribing physician. Reports available include but are not limited to:

- a. detailed inmate/patient profiles;
- b. patient drug allergy and drug interaction alert;
- c. monthly drug usage per inmate/patient;
- d. drug utilization report;
- e. continual narcotic controlled substances inventory;
- f. monthly psychotropic usage report;
- g. Computerized Medical Administration Record, delivered to the institution five (5) days before the end of the calendar month;
- h. list of inmates/patients taking medications which are known to produce adverse side-effects when they are exposed to high temperatures or the sun;
- i. total doses per inmate/patient dispensed;
- j. percentage of inmates/patients on medications;
- k. percentage of inmates/patients on psychotropics; formulary vs. non formulary medications dispensed;
- m. number of prescriptions per inmate/patient;
- n. high to low usage by dollar amount;
- o. high to low usage by quantity dispensed;
- p. medication breakdown listed by specific physician;
- q. medication classification report;
- r. cost containment recommendation report;
- s. side effect and drug interaction report;
- t. stop date report;
- u. invoices containing drug name, NDC and AWP; and
- v. numerous customized management/cost containment reports.

## **16. Pharmacy and Therapeutics Committee (P & T Committee)**

Contractor will serve as a member (and chair, if requested) of the Correctional Health Services Pharmacy and Therapeutics committee. Contractor will also be available to provide consultation to the prescribing physicians and nurses in relations to pharmaceutical therapy. During quarterly on-site visits, Contractor will also discuss topics including the quarterly inspections, drug



regimen reviews and formulary management. Contractor will also provide minutes for P & T Committee within 15 days of the meeting.

### **17. Self-Medication Program**

Contractor will review and monitor County's self-medication program in conjunction with the nursing staff.

### **18. Quarterly Inspections**

Contractor will be provided on site at the facility on a quarterly basis or as required. Contractor may elect to subcontract this function with the prior written approval of County. During these quarterly visits, Contractor, or its designee, will:

- A.** assist in developing, implementing, monitoring, and updating County's policies, procedures and protocols for the safe, effective distribution, control, administration and use of medications complying with all regulations the facility;
- B.** ensure the facility complies with all applicable state and federal regulations regarding dispensing, administering, and procuring pharmaceuticals;
- C.** set up a system to insure that all pharmaceuticals are tracked and recorded to show accountability;
- D.** provide routine inspections to insure that the facility complies with all current pharmacy regulations;
- E.** conduct an overall inspection of the medications room of the facility;
- F.** inspect the contents of the emergency medication kit and poison antidote kit and replace any outdated and/or deteriorated items;
- G.** ensure compliance of all federal, state, and locals laws and regulations in regards to the guidelines of your Correctional Health Services, Controlled Substance Act, and the State Pharmacy Boards;
- H.** provide County with signed and dated documentation of quarterly inspections including recommendations made, corrective actions implemented or problems observed and a written report will be provided to your facility;
- I.** assist County in the accounting, reconciliation, and disposal/removal of unused controlled substances as outlined by federal, state, and local laws and regulations. Count sheets will be provided for strict accountability and all documentation will be enforced as required by law;
- J.** inspect all areas relating to pharmacy including medication records, storage and security;
- K.** monitor the self medication program with the nursing staff;
- L.** provide continual assessment of recommendation of plans for implementations. This will be completed through the quarterly inspection reports that are provided to the administrator and nursing staff for follow up and evaluation of performance;
- M.** provide all other responsibilities required, as set forth in federal or state laws, statutes, or regulations presently enacted, or may hereafter be enacted, as well as provided, detailed services applicable to the facility; and
- N.** provide consultant pharmacists who are available to County continuously for

emergency and routine consultations twenty-four (24) hours a day, seven (7) days a week.

## **19. Data Requirements**

Contractor will work with the technology staff to develop a mutually acceptable data system which will assure that all required data collected regarding the pharmacy services provided to jail inmate/patients will be electronically transferred into the Health Services information system.

## **20. Additional Products Available**

In addition to pharmaceutical services, County may, from time to time, wish to purchase the following:

- A. durable medical equipment and health aids (i.e. crutches, canes, braces, walkers, wheelchairs, wound care products, urologicals, etc.);
- B. over the counter / health and beauty aids (i.e. aspirin, Tylenol, shampoos, hand lotions, disinfectant cream, etc.);
- C. IV solutions and mixtures; and

respiratory therapy services including respiratory therapists, technicians, products and equipment.

## **21. Smooth Transition to New Services**

Contractor will provide a start-up schedule, which covers the initial inservice of staff prior to the change of service, a time frame for all transitional activities, and resolution of identified problems. In addition to the staff inservice, Contractor will gather prescription information, inspect the med room, set up a medication ordering/distribution system obtain physician information, install a fax machine, etc.

### **B. PROVISION OF 340B PHARMACEUTICALS**

#### **1. Covered 340B Drugs.**

The prescription outpatient drugs covered by this Agreement (hereinafter "**Covered 340B Drugs**") include "Legend" drugs, that is those drugs which by federal law can be dispensed only pursuant to a prescription and which are required to bear the legend "Caution – Federal Law prohibits dispensing without prescription." Other qualified prescriptions include insulin (on prescription only) and over the counter medications as long as prescribed by an authorized medical provider. All Covered 340B Drugs purchased under this Agreement are the property of County. All Covered 340B Drugs subject to this Agreement are also subject to the Limiting Definition of "covered outpatient drug" set forth in Section 1927(k) of the Social Security Act, 42 USC 1396r-8(k) (2) & (3), which is incorporated as the applicable definition for the section of the 1992 Veterans Affairs Act that created Section 340B of the Public Health Services Act.

## 2. Eligible Patients.

Only patients of Correctional Health Services are eligible or receive Covered 340B Drugs from Contractor (“**Eligible Patients**”). Few of Correctional Health Services’ patients receive Medi-Cal benefits. Medication for Medi-Cal eligible patients will not be ordered from Contractor. Under no circumstances will Contractor dispense Covered 340B Drugs to anyone other than Eligible Patients of County. County will follow current ordering procedures for all medications as delineated in A.5. Contractor will use 340B medications to fill patient specific orders for all patients’ medications that cannot be billed to a third party payor at the time of dispensing whenever the ordered medication is available on the 340B or Prime Vendor contract price list, following the same procedures detailed in A 6. 7. and 8 with the exception of starter packs.

## 3. Restocking and Inventory Maintenance.

3.1 Restocking. Contractor agrees to place orders as necessary with one or more pharmaceutical suppliers (“**SUPPLIER**”) to maintain and replenish the drugs consumed pursuant to this Agreement as often as determined by the Contractor. County and Contractor shall arrange with SUPPLIER to ship directly to Contractor. Contractor shall provide County a copy of each and every order so placed, as well as shipping orders and invoices showing prices Contractor is responsible for the receipt of 340B Drugs purchased by Covered Entity. Upon receipt of 340B Drugs, Contractor shall compare all shipments received on behalf of Covered Entity and confirm that the shipments conform to the orders of 340B Drugs placed by Covered Entity. If Contractor should find a discrepancy between the shipment and order of 340B covered outpatient drugs, Contractor shall inform Covered Entity **within five (5) business days** of this discrepancy.

3.2 Inventory. Contractor shall conduct a complete and accurate inventory of all Covered 340B Drugs on the last business day OR the 30th of June of each year and provide an electronic file in Excel compatible format within 5 days of conducting the inventory. Contractor shall maintain an inventory of expired or otherwise unusable Covered 340B Drugs and provide that inventory in electronic file in Excel compatible format within 5 days of conducting the annual inventory. Expired or otherwise unusable Covered 340B Drugs shall be disposed of in compliance with state, local or federal regulations.

## 3.3 Inventory Maintenance.

Contractor agrees to maintain a stock of Covered 340B Drugs physically separate from its other drug inventory, and to protect its inventory of Covered 340B Drugs against intentional or unintentional dispensing to anyone other than Eligible Patients, and to reduce the possibility of this or other occurrences of drug diversion. Medications for eligible patients will be dispensed from Contractor’s inventory. At regularly scheduled intervals, Contractor will place an order using the Covered Entity 340B account with the Supplier to replenish those medications. Contractor and Director of Correctional Health or designee will meet quarterly to reconcile the payment for medications dispensed that cannot be replaced. If during the quarter, total dispenses of a certain medication do not equal the package size of the drug to be replaced, Contractor

agrees to bill County the actual acquisition cost for those medications, or County and Contractor may agree to purchase a container of medications to replace Contractor's inventory and the remainder shall be kept for future dispenses. Contractor shall maintain such records as are adequate to permit it to prepare the reports required under paragraph 6 hereof, and to permit County, DHHS, or any eligible drug manufacturer to determine upon audit to whom such Covered 340B Drugs have been dispensed. Upon termination of this Agreement, Contractor shall deliver all unused items of inventory purchased by or on behalf of County hereunder to County, if County has a valid permit, or, in the absence of such a permit, return them to SUPPLIER for County's credit, if possible, or destroy them, if they cannot be returned or transferred within thirty days following termination.

**4. Establishment and Maintenance of Tracking System.**

- a. Contractor, with the assistance of Covered Entity, shall establish and maintain a Tracking System suitable to prevent the diversion of 340B Drugs to individuals who are not Covered Entity Patients. The Tracking System shall include monthly sample comparisons of Covered Entity Patient prescriptions to the dispensing records and a monthly comparison of 340B Drug purchasing and dispensing records.
- b. Covered Entity will verify, using Contractor'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 Covered Entity. Such records may include: Prescription files, velocity reports, and records of ordering and receipt, or other documentation agreed upon by the Parties.
- c. Prior to the provision of pharmacy services by Contractor pursuant to the Agreement, Covered Entity shall have the opportunity, upon reasonable notice and during business hours, to examine the Tracking System.
- d. Contractor shall make any and all adjustments to the Tracking System that Covered Entity determines are reasonably necessary to prevent the diversion of 340B Drugs to individuals who are not Covered Entity Patients.

**5. Prohibition Against Diversion.**

Covered Entity and Contractor shall not resell or transfer 340B Drugs to any individual or any other entity who is not a Covered Entity Patient. If Covered Entity reasonably determines within 90 days that Contractor has violated the prohibition against the diversion of 340B Drugs, Contractor shall pay Covered Entity the applicable amount of the 340B discount so that Covered Entity may reimburse the drug manufacturer for this amount of the 340B discount.

**6. Payment to SUPPLIER by County.**

County agrees to timely pay SUPPLIER amounts owing to SUPPLIER for Covered 340B Drugs purchased hereunder. In the event that SUPPLIER is not paid and does not ship Covered 340B Drugs in sufficient quantity to Contractor, Contractor shall notify County in writing of its lack of 340B Drugs, and, if CLINIC continues to write prescriptions for Contractor to fill, may thereafter, in its sole discretion, fill prescriptions from its non-340B inventory, and charge for its own account Eligible Patients or County according to its own, non-340B prices as described in paragraph Section A of this Exhibit, or Contractor may refuse to fill prescriptions of County, until satisfactory arrangement is made by County.

**7. Payments to Contractor by County.**

Contractor Dispensing Fee. Contractor and County agree that Contractor shall receive a Dispensing Fee as specified in Exhibit B, for each prescription of Covered 340B Drugs filled for Eligible Patients and that such Dispensing Fee covers Contractor's costs and, in addition to delivery fees, constitutes the sole and exclusive payment Contractor is entitled to receive hereunder. Contractor will add dispensing fees to the monthly invoice submitted as detailed in Exhibit B.

**8. Reports.**

Attached to the monthly billing invoice, Contractor shall transmit to County a detailed report, in Excel compatible format showing each Eligible Patient served, the prescription filled, with specific details about each claim, including the drug name, strength, unit dose, appropriate identification codes, manufacturer, quantity dispensed, amount charged and collected, for the previous month (example attached).

**9. Maintenance of Records and Reports.**

- a. Contractor will provide Covered Entity with reports consistent with customary business practices (e.g., billing statements, receiving and dispensing records).
- b. Contractor shall ensure that all reimbursement accounts and dispensing records, and any and all other pertinent records relating to Contractor's responsibilities and duties under the Agreement, are maintained by Contractor separately from Contractor's own operations and will be made available to Covered Entity, HRSA, and the manufacturer in the case of an audit.
- c. On behalf of Covered Entity, Contractor shall maintain all relevant records relating to the pharmacy services associated with 340B Drugs and Covered Entity Patients, in accordance with applicable Federal, State, and local laws and regulations, including but not limited to the Federal Standards for the Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164). Contractor shall maintain all auditable records for a period of time that complies

with all applicable Federal, State and local requirements, in any event not less than a period of ten (10) years.

- d. Contractor shall provide Covered Entity with reasonable access to Contractor's business records relating to pharmacy services for 340B Drugs, as is deemed necessary by Covered Entity in order to ensure that Contractor is in compliance with applicable Federal, State, and local laws, regulations, and requirements.
- e. Covered Entity and Contractor understand that they are subject to audits by outside parties (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.
- f. Upon request, Covered Entity and Contractor shall disclose or permit inspection of any records or information relating to the Agreement, when necessary to comply with audits or investigations conducted by the Federal or State governments.
- g. Upon request, Contractor shall provide reasonable access by a drug manufacturer that sells 340B Drugs to Covered Entity to relevant records and materials for purposes of any audits conducted by the drug manufacturer relating to 340B Drugs in accordance with manufacturer audit guidelines as set forth at 61 Fed. Reg. 65406-65413 (December 12, 1996).
- h. Covered Entity and Contractor will identify the necessary information for the Covered Entity to meet its ongoing obligations of ensuring that the requirements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the Covered Entity. Information regarding the functioning of the independent audits and any information to be made available to the independent auditor are described in **Exhibit B**.
- i. Upon written request to the Covered Entity, a copy of this Agreement will be provided to the Office of Pharmacy Affairs.

#### **10. Maintenance of Records.**

Contractor will preserve all records of shipment, receipts, and dispensing of 340B drugs for audit at any reasonable time for a period of three years following date of provision of services. It is understood by both parties under this Agreement that, under Section 340B(a)(5)(C) of the PHS Act, they are subject to audit by the drug manufacturers and the U.S. Public Health Service of DHHS of records that directly pertain to compliance with the Act.

#### **11. Contractor Compliance Responsibility.**

Contractor shall be solely responsible for all professional advice and services rendered by it for

the Eligible Patients. Contractor is responsible for and agrees to render services as herein provided in accordance with the rules and regulations of the California State Board of Pharmacy [or other applicable state, if Contractor is located in such state], all laws of the State of California, and all applicable laws and regulations resulting from the Veteran's Health Care Act of 1992 (P.L. 102-585, sec 602). It is expressly understood that relations between the Eligible Patients and Contractor shall be subject to the rules, limitations, and privileges incident to the pharmacy-patient relationship. Contractor shall be solely responsible, without interference from the County or its agents to said Eligible Patient for pharmaceutical advice and service, including the right to refuse to serve any individual where such service would violate pharmacy ethics or any pharmacy laws or regulations.

**12. Self Reporting Requirements.**

In the event that Covered Entity determines that 340B drug diversion or duplicate discounts have occurred or that it is otherwise unable to comply with its responsibility to ensure reasonable compliance, then it must take immediate remedial action to assure compliance and notify HRSA's Office of Pharmacy Affairs (OPA) regarding such compliance problems and actions taken to remedy those problems.

**13. Insurance.**

Contractor shall at its own expense maintain a policy of insurance covering professional acts and omissions with a licensed insurance carrier to be in an amount not less than one million dollars (\$1,000,000) per incident and three million dollars (\$3,000,000) in the aggregate, and said policy shall be maintained during the term of this agreement. Contractor shall cause its insurer to name County as an additional named insured on such policy, and shall provide County with a certificate to such effect.

**14. Indemnification.**

14.1 County shall indemnify, defend and hold harmless Contractor from any and all liability, loss, claim, lawsuit, injury, cost, damage or expense whatsoever (including reasonable attorneys fees and court costs) arising out of, incident to or in any manner occasioned by the performance or nonperformance of any duty or responsibility under this Agreement, by County or any of its employees, agents, contractors or subcontractors.

14.2 Contractor shall indemnify, defend and hold harmless County from any and all liability, loss, claim, lawsuit, injury, cost, damage or expense whatsoever (including reasonable attorneys fees and court costs) arising out of, incident to or in any manner occasioned by the performance or nonperformance of any duty or responsibility under this Agreement, by Contractor or any of its employees, agents, contractors or subcontractors.

14.3 Without limiting any other indemnification provisions set forth in this Agreement, neither party shall be liable to the other party pursuant to this Section for any claim covered by insurance, except to the extent that the liability of such party exceeds the amount of such insurance coverage.

**15. Medicaid Prescriptions.**

Notwithstanding anything herein to the contrary, Contractor will not use Covered 340B Drugs to dispense prescriptions paid for by the state MediCal agency or the Health Plan of San Mateo. County represents that Correctional Health Services does not have many MediCal or Medicaid Eligible patients in its care. To the extent that there are any Medi-Cal eligible patients, Correctional Health Services will order medications for these individuals from a separate local pharmacy.

When a Medicaid agency pays for drugs for its beneficiaries, it is generally entitled to claim a rebate from the drug manufacturer, to reduce its effective cost to a statutorily established price. Section 340B extends a similar price to Covered Entities, and requires that there be a mechanism to protect drug manufacturers from Medicaid rebate claims for Covered 340B Drugs purchased pursuant to Section 340B. To avoid any chance that a State Medicaid agency will pay for 340B Drugs purchased hereunder and then submit prohibited rebate claims to the drug manufacturers, Contractor agrees not to order medications for Medi-Cal eligible patients from Contractor.

Medications dispensed for eligible patients who are covered under the Aids Drug Assistance Program (ADAP) shall be dispensed from contractor's inventory and billed to ADAP. For eligible patients who become eligible for ADAP after medications have been dispensed, contractor may not retroactively re-bill ADAP for those medications dispensed. County will be billed according to Exhibit B.

**16. Inspection by Manufacturer.**

Contractor and County understand and agree that a copy of this Agreement will be provided, upon request, to a drug manufacturer who has signed a purchasing agreement with DHHS. In the event either party receives such a request, it shall immediately inform the other party.

**17. Non-Assignment.**

This Agreement may not be assigned by either party without the prior written agreement of the other party.

**18. Entire Agreement.**

This Agreement represents the entire understanding of the parties. There are no other agreements or understandings between the parties, either oral or written, relating to Covered 340B Drugs. Any amendments to this Agreement shall be in writing and signed by both parties.



**All other terms and conditions of the agreement dated June 28, 2005, and as amended on May 20, 2008 between the County and Contractor shall remain in full force and effect.**

**Provision of 340B Pharmaceuticals by Contractor may commence as early as April 5, 2010, and no later than April 15, 2010.**

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

COUNTY OF SAN MATEO

By: \_\_\_\_\_  
President, Board of Supervisors, San Mateo County

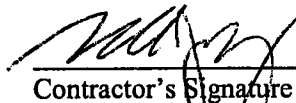
Date: \_\_\_\_\_

ATTEST:

By: \_\_\_\_\_

**Clerk of Said Board**

Diamond Pharmacy Services

  
\_\_\_\_\_  
Contractor's Signature

Date: 4/2/10

FA0247696

11/2/2009 DIAMOND

PLAN	Rx number	DATE DISPENSED	LAST, FIRST	QTY DISPENSED	MEDICATION DISPENSED	PROVIDER	NDC	PT. ID NUMBER
C60S	1000001	10/13/2009	LAST, FIRST	2	ASCENSIA CONTOUR STRP TES 50 BAYER	LAST, FIRST	193708050	W7510606A00
C60T	1000002	10/13/2009	LAST, FIRST	100	MICROLET BAYER	LAST, FIRST	193654621	W7510606A00
CZ55	1000003	10/13/2009	LAST, FIRST	100	LOVASTATIN* 20MG TAB LUPIN	LAST, FIRST	68180046803	1062900

# EXAMPLE OF 340B REPORT

**County of San Mateo  
Contractor's Declaration Form**

**I. CONTRACTOR INFORMATION**

Contractor Name:	Diamond Drugs, Inc	Phone:	724-349-1111
Contact Person:	Mark J Zilner, R.Ph	Fax:	724-349-2604
Address:	645 Kolter Drive Indiana PA 15701		

**II. EQUAL BENEFITS (check one or more boxes)**

*Contractors with contracts in excess of \$5,000 must treat spouses and domestic partners equally as to employee benefits.*

- Contractor complies with the County's Equal Benefits Ordinance by:
  - offering equal benefits to employees with spouses and employees with domestic partners.
  - offering a cash equivalent payment to eligible employees in lieu of equal benefits.
- Contractor does not comply with the County's Equal Benefits Ordinance.
- Contractor is exempt from this requirement because:
  - Contractor has no employees, does not provide benefits to employees' spouses, or the contract is for \$5,000 or less.
  - Contractor is a party to a collective bargaining agreement that began on \_\_\_\_\_ (date) and expires on \_\_\_\_\_ (date), and intends to offer equal benefits when said agreement expires.

**III. NON-DISCRIMINATION (check appropriate box)**

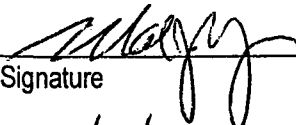
- Finding(s) of discrimination have been issued against Contractor within the past year by the Equal Employment Opportunity Commission, Fair Employment and Housing Commission, or other investigative entity. Please see attached sheet of paper explaining the outcome(s) or remedy for the discrimination.
- No finding of discrimination has been issued in the past year against the Contractor by the Equal Employment Opportunity Commission, Fair Employment and Housing Commission, or any other entity.

**IV. EMPLOYEE JURY SERVICE (check one or more boxes)**

*Contractors with original or amended contracts in excess of \$100,000 must have and adhere to a written policy that provides its employees living in San Mateo County up to five days regular pay for actual jury service in the County.*

- Contractor complies with the County's Employee Jury Service Ordinance.
- Contractor does not comply with the County's Employee Jury Service Ordinance.
- Contractor is exempt from this requirement because:
  - the contract is for \$100,000 or less.
  - Contractor is a party to a collective bargaining agreement that began on \_\_\_\_\_ (date) and expires on \_\_\_\_\_ (date), and intends to comply when the collective bargaining agreement expires.
  - We have no employees in San Mateo County

**I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that I am authorized to bind this entity contractually.**

  
 Signature \_\_\_\_\_  
 3/19/08  
 Date \_\_\_\_\_

MARK J. ZILNER  
 Name \_\_\_\_\_  
 DIRECTOR OF OPERATIONS  
 Title \_\_\_\_\_