

EXHIBIT A

STATEMENT OF WORK FOR CONTROLLED SUBSTANCES SUPPLY FOR PARAMEDIC PROVIDER AGENCIES

TABLE OF CONTENTS

SECTION	TITLE	PAGE
1.0	SCOPE OF WORK	1
2.0	COUNTY RESPONSIBILITIES.....	1
2.1	RESPONSIBILITIES OF THE EMERGENCY MEDICAL SERVICES (EMS) AGENCY	1
2.2	RESPONSIBILITIES OF THE COUNTY-OPERATED HOSPITAL.....	2
2.3	RESPONSIBILITIES OF THE OFFICE OF THE PHARMACY DIRECTOR ...	2
3.0	CONTRACTOR RESPONSIBILITIES	3
3.1	CONTRACTOR RESPONSIBILITIES	3
3.2	AVAILABILITY OF PERSONNEL, FACILITIES, PROTOCOLS	4
3.3	MATERIALS AND EQUIPMENT	4
3.4	TRAINING	5
4.0	ADDITIONS AND/OR CHANGES IN AGREEMENT TERMS OR REIMBURSEMENT RATES	5

EXHIBIT A

STATEMENT OF WORK (SOW)

1.0 SCOPE OF WORK

Since the mid 1990's, the EMS Agency has been responsible for the cost of approved Controlled Substances obtained from County-operated pharmacies by paramedic provider agencies. The Controlled Substances Supply for Paramedic Provider Agencies Agreement is intended to offset the EMS Agency's costs of dispensing approved Controlled Substances to contracted providers of Advanced Life Support (ALS) prehospital emergency medical services by licensed and accredited Emergency Medical Technicians-Paramedics (EMT-P).

2.0 RESPONSIBILITIES The County's and the Contractor's responsibilities are as follows:

COUNTY

2.1 RESPONSIBILITIES OF THE EMERGENCY MEDICAL SERVICES (EMS AGENCY)

- 2.1.1 Maintain policies and procedures consistent with State and County statutes, regulations, and standards for the procurement, transport, storage, distribution, administration, and monitoring of approved Controlled Substances, including narcotics. Current policies and procedures are reflected in Exhibit B, Prehospital Care Manual (Reference No. 702). Such policies shall be reviewed at least every three (3) years and revised as necessary to remain consistent with legal requirements.
- 2.1.2 Maintain a standardized inventory of approved controlled drugs carried on ALS Units ("Inventory") consistent with the paramedic scope of practice. Such Inventory shall be reviewed at least every three (3) years and revised as necessary to remain consistent with the paramedic scope of practice.
- 2.1.3 Assess compliance with the policies and procedures specific to procurement, transport, storage, distribution, administration and monitoring of approved Controlled Substances by performing periodic retrospective audits of records and by periodically observing the activity on a first-hand basis. Such observations may be performed on either an announced or unannounced basis.
- 2.1.4 With Contractor's Project Manager or their designee, review this Agreement on not less than an annual basis to ensure applicability to then current conditions, policies, procedures, and protocols specific to supply and resupply of approved Controlled Substances.

- 2.1.5 Inform Contractor of manufacturer's recall of approved Controlled Substances dispensed, as applicable.

2.2 RESPONSIBILITIES OF THE COUNTY-OPERATED HOSPITAL PHARMACY

- 2.2.1 Maintain a consistent and adequate supply of approved Controlled Substances available to meet County dispensing requirements.
- 2.2.2 Provide a mechanism for after-hours emergency dispensing of approved Controlled Substances.
- 2.2.3 Provide monthly report to the Office of the Department of Health Services (DHS) Pharmacy Director of approved Controlled Substances specified in Exhibit C, Controlled Substances Inventory, dispensed to Contractor. If applicable, said report will also include any fines assessed against the County by the California State Board of Pharmacy that are a direct result of noncompliance with State Law or a direct result of actions or omissions by the Contractor.
- 2.2.4 Provide accurate and timely data to the Office of the DHS Pharmacy Director for oversight and monitoring on a monthly basis.
- 2.2.5 Provide sixty (60) day, or earlier whenever practicable, advance written notice to the Contractor, Office of the DHS Pharmacy Director, and the EMS Agency of any operational changes that would affect the procurement of approved Controlled Substances, prior to implementation.
- 2.2.6 Maintain operation logs/tracking system with the capability to track approved Controlled Substances dispensed to Contractor and by individual unit.
- 2.2.7 Maintain system-wide data collection and the ability to provide data at the request of the EMS Agency or Contractor.

2.3 RESPONSIBILITIES OF THE OFFICE OF THE DHS PHARMACY DIRECTOR

- 2.3.1 Provide sixty (60) day, or earlier whenever practicable, advance written notice to Contractor, County-operated Hospital Pharmacy, and the EMS Agency of any operational changes that would affect the procurement of approved Controlled Substances, prior to implementation.
- 2.3.2 Notify the EMS Agency of manufacturer's recall of approved Controlled Substances, as applicable.
- 2.3.3 Provide accurate and timely data to HS Finance for invoice processing.

3.0 CONTRACTOR RESPONSIBILITIES

Contractor will administer the Agreement according to the Agreement, Paragraph 7.0, Administration of Agreement - Contractor. Specific duties shall include:

3.1 CONTRACTOR RESPONSIBILITIES

- 3.1.1 Adhere to policies and procedures consistent with State and County statutes, regulations, and standards for the procurement, transport, storage, distribution, administration, and monitoring of approved Controlled Substances, including narcotics. Current policies and procedures are reflected in Exhibit B Prehospital Care Manual (Reference No. 702).
- 3.1.2 Adhere to all policies and procedures of the EMS Agency as outlined in the EMS Agency's Prehospital Care Policy Manual pertaining to the supply and resupply of ALS units or other responding units providing prehospital medical care.
- 3.1.3 Procure, transport, store, administer and monitor only those approved Controlled Substances listed in Exhibit C, Controlled Substances Inventory, including any modifications thereto which may be implemented at a later date, to remain consistent with the paramedic scope of practice.
- 3.1.4 Maintain policies and procedures for the procurement, transport, storage, administration, and monitoring of approved Controlled Substances as defined herein. Such policies and procedures shall be submitted to the EMS Agency Medical Director for review and approval. Any subsequent changes to policies and procedures must be submitted to the EMS Agency for review and approval prior to implementation.
- 3.1.5 Implement and maintain a quality assurance program referencing approved Controlled Substances, which includes the mechanisms for overseeing the procurement, transport, storage, administration, and monitoring of approved Controlled Substances.
- 3.1.6 Permit the EMS Agency Medical Director or his designee(s) to make scheduled reviews of Contractor's policies and procedures and quality assurance program as it pertains to the procurement, transport, storage, administration, and monitoring of approved Controlled Substances, and, upon request, make available results of audits and investigations to the EMS Agency Medical Director or his designee(s) during the term of this Agreement.
- 3.1.7 Comply with periodic announced and unannounced site visits by County, State of California, or federal representatives to perform surveys and reviews to ensure compliance with State and federal laws and regulations and local policies pertinent to the procurement, storage,

transport, administration, and monitoring of approved Controlled Substances. Monitoring may include testing of approved Controlled Substances.

- 3.1.8 Reimburse Los Angeles County DHS for any fines assessed against the County by the California State Board of Pharmacy, or other regulatory agencies, that are a direct result of noncompliance with State Law or a direct result of actions or omissions by the Fire Department.
- 3.1.9 Reimburse Los Angeles County DHS for the cost of Controlled Substance testing if tampering or diversion is suspected and confirmed after an investigation is conducted. Fire Department will not be charged if tampering or diversion is not confirmed.
- 3.1.10 Provide the EMS Agency Medical Director or his designee(s) with copies of all Contractor EMS records and logs associated with approved Controlled Substances in compliance with Exhibit B, Prehospital Care Manual (Reference No. 702). All such records and logs shall be retained at a location in Los Angeles County by Contractor for the minimum period of time required by law and by Exhibit B, Prehospital Care Manual (Reference No. 702).
- 3.1.11 Provide sixty (60) day, or earlier whenever practicable, advance written notice to the County-operated Hospital Pharmacy, Office of the DHS Pharmacy Director, and the EMS Agency of any operational changes that would affect the procurement of approved Controlled Substances.
- 3.1.12 Inspect inventory of approved Controlled Substances to ensure doses containing recalled lot numbers are immediately removed and disposed of in accordance with instructions provided once notification of manufacturer's recall is received from the EMS Agency.
- 3.1.13 Complete and submit Novation Affiliate Purchasing Program Agreement, Exhibit J of the Agreement, within thirty (30) days of agreement execution.

3.2 Availability of Personnel, Facilities, Protocols

Contractor shall make its personnel, facilities, and medical protocols available to assist Director or his designee, or State representative(s), or both, to verify compliance with applicable standards and regulations and with the terms of this Agreement.

3.3 Materials and Equipment

The purchase of all materials/equipment to provide the needed services is the responsibility of Contractor.

3.4 Training

- 3.4.1 Contractor shall provide training programs for all new employees and continuing in-service training for all employees handling approved Controlled Substances. All new employees shall review Ref. No. 702, Controlled Drugs Carried on ALS Units, and sign a statement that they have read and understood the policy. Signed statements must be kept on file and made available to County staff upon request.
- 3.4.2 All employees involved in the handling and distribution of approved Controlled Substances shall be trained in their assigned tasks and in the safe handling of approved Controlled Substances.

4.0 ADDITIONS AND/OR CHANGES IN AGREEMENT TERMS OR REIMBURSEMENT RATES

All changes must be made in accordance with sub-paragraph 8.1 Amendments of the Agreement.

DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: CONTROLLED DRUGS CARRIED ON ALS UNITS

(PARAMEDIC)
REFERENCE NO. 702

PURPOSE: To ensure accountability for all controlled drugs issued to ALS units.

AUTHORITY: Health and Safety Code, Chapter 5, 1797.220 and 1798
California Business and Professions Code, Section 4005 and 4119(4)(5)
DEA Regulations, Title 21, Code of Federal Regulations, Section 1300-1360
Controlled Substances Act, 21 USC 801-890

PRINCIPLES:

1. Effective controls and procedures are essential to guard against theft and diversion of controlled substances due to the risks associated with mishandling these drugs.
2. Controlled drugs will be restocked only with a full account of drugs administered, wasted, or lost.
3. Controlled drugs issued from County-operated pharmacies are intended for use within Los Angeles County except as otherwise specified in this policy. County-issued controlled drugs remain the property of Los Angeles County after being issued to paramedic provider agencies and when carried on ALS units.

QUANTITIES OF CONTROLLED DRUGS TO BE CARRIED ON ALS UNITS:

Morphine sulfate: 4mg unit dose, minimum amount 32mg not to exceed 60mg unless otherwise approved by the EMS Agency Medical Director, the Provider Agency Medical Director or as dictated by supply.

Midazolam (Versed®): 5mg unit dose, minimum amount 20mg not to exceed 40mg unless otherwise approved by the EMS Agency Medical Director, the Provider Agency Medical Director, the Provider Agency Drug Authorizing Physician or as dictated by supply.

POLICY:

- I. Provider Agencies May Obtain Controlled Drugs Through:
 - A. A County operated hospital pharmacy utilizing the procedure outlined in this policy.
 - B. A Provider Agency Medical Director who meets the qualifications of Reference No. 411, Provider Agency Medical Director, if they agree to authorize such procurement, or a Provider Agency Drug Authorizing Physician.

EFFECTIVE: 1-7-98
REVISED: 08-01-10
SUPERSEDES: 07-1-09

PAGE 1 OF 6

APPROVED:


Director, EMS Agency


Medical Director, EMS Agency

II. Controlled Drug Resupply Through a County Operated Hospital:

A. County (EMS Agency) responsibilities:

1. Assign each provider agency that chooses to resupply controlled drugs through a County-operated hospital to one or more County facilities.
2. Supply each provider agency with a locked bag in which to store controlled drugs while in transit between the pharmacy and the provider agency.
3. Resupply controlled drugs on a one-for-one basis utilizing the procedure outlined in this policy.
4. Report the theft or loss of any controlled substances to the issuing pharmacy, whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

B. Provider Agency Responsibilities:

1. Provider agency controlled drug policies and procedures shall be submitted to the EMS Agency for initial review and approval.
 - a. Any subsequent changes to policies and procedures must be submitted to the EMS Agency for review and approval.
2. Provide the County pharmacists with the names and original signatures of individuals authorized to pick up and transport controlled drugs.
 - a. Submit a single list of names (not copies of drivers' licenses or other ID cards) on departmental or company letterhead.
 - b. Update the list annually, no later than June 30th, and provide a copy to the EMS Agency.
3. Identify, in the provider agency's internal policy, one or more individuals responsible for the key to the controlled drug transit bag. The County pharmacist will maintain a second key at the pharmacy.
4. Ensure that the on-duty paramedic is responsible for the security of the drugs at all times. If the department uses a non-key system, such as a keypad or padlock type, the internal controlled substance policy should indicate how the combination is kept secure. Ensure adequate security to guard against theft and diversion during controlled drug transport and distribution.
5. Utilize County-issued controlled drugs outside of Los Angeles County only in the event of wildfires, disasters, terrorist responses or other unanticipated events.
6. Restock controlled drugs only from the assigned Department of Health Services (DHS) pharmacy to prevent intermingling of controlled drug stock.

C. Replacement Procedure for Controlled Drugs Administered in the Field:

1. Providers shall:

- a. Present the blue copy of the EMS Report Form, or an EMS Agency approved electronic patient care record (ePCR) for each patient to whom a controlled drug was administered.
- b. Present a photo identification (employee ID, driver's license, etc.) to verify identity at the pharmacy.

2. Pharmacists shall:

- a. Stamp and initial the blue copy of the EMS Report Form (or an EMS Agency approved ePCR) utilizing the EMS Agency-issued stamp.
- b. Replace the controlled drugs utilizing the locked transport bag.
- c. Return the blue copy (or an EMS Agency approved ePCR) to provider agency personnel.

D. Replacement Procedure for Missing, Broken, Lost or Expired Controlled Drugs:

1. Provider agencies shall:

- a. Complete Reference No. 702.1, Missing/Expired Controlled Drug Pharmacy Reporting Form, and maintain a copy in the provider agency's controlled drug file.
- b. Present the completed Reference No. 702.1 to the issuing pharmacy along with the expired drug(s) for disposal in accordance with all applicable state and federal regulations.

2. Pharmacists shall:

Replace the controlled drug following their facility's approved procedure.

E. Replacement Procedure when the Blue Copy of the EMS Report Form (or the ePCR) is Missing:

1. Paramedics shall notify the on-duty captain, battalion chief or supervisor that the blue copy is missing. A written report summarizing the incident shall be submitted to the EMS Agency that:

- a. Describes what happened to the Blue Copy of the form (or the ePCR).
- b. Is signed and dated by the reporting party, the on-duty captain or supervisor, the battalion chief or general manager.

2. The incident report and a copy of the EMS Report Form shall be forwarded to the paramedic coordinator or the individual responsible for controlled drug procurement.

3. The paramedic coordinator/responsible individual shall review the documents and hand deliver copies to the EMS Agency.

4. EMS Agency staff shall review the documents and generate a letter to the provider agency's assigned County pharmacy authorizing replacement of the controlled drugs. The original copy of the authorization, which expires in 14 days, is handed to the paramedic coordinator/responsible individual to carry to the pharmacy.

III. Controlled Drug Replacement Through a Non-County Supplier:

- A. Provider agencies shall develop policies and procedures, approved by their Provider Agency Medical Director and/or Drug Authorizing Physician to ensure that all controlled drugs are obtained, maintained, and distributed in a secure manner consistent with local, state, and federal regulations.
- B. Such policies and procedures shall be submitted to the EMS Agency for review and approval unless the Provider Agency Medical Director/Drug Authorizing Physician wants to assume sole responsibility for procurement, storage and security of controlled substances. In that case, the Provider Agency Medical Director and Provider Agency Fire Chief (or CEO/President) shall submit Ref. No. 702.4, Provider Agency Medical Director Notification of Controlled Substance Program Implementation.

IV. Controlled Drug Security

- A. Controlled drug security requirements apply to all provider agencies, whether drugs are ordered through the Provider Agency Medical Director, Drug Authorizing Physician or the EMS Agency Medical Director.
- B. Paramedics assigned to an advanced life support (ALS) unit shall be responsible for maintaining the correct controlled drug inventory and security of the narcotic keys (or confidentiality of the keypad/padlock combination) for their assigned unit at all times.
- C. Controlled drugs shall not be stored in any location other than on ALS units unless authorized by the EMS Agency. Provider agencies authorized by the EMS Agency to store controlled drugs off the ALS unit shall specify in their internal policy the location, security, access and procedure for obtaining drugs from the controlled drug cache.
- D. Morphine and midazolam shall be secured on the ALS units under double lock.
- E. Daily Inventory Procedures
 1. Controlled drugs shall be inventoried by two paramedics at least daily and anytime there is a change in personnel.
 2. The key to access controlled drugs shall be in the custody of the individual who performed the inventory.
 3. The Daily Controlled Drug and Key Inventory Form, Reference No. 702.2 or its equivalent, shall be co-signed with the names of the relinquishing and the receiving paramedic. Entries shall be in blue or black ink only.

NOTE: Errors shall be corrected by drawing a single line through the incorrect wording; the writing underneath the single line must remain readable. The individual making the change should initial adjacent to their correction. Correction fluid or other erasure material is not permitted.

4. The Daily Controlled Drug and Key Inventory Form, Reference No. 702.2 or its equivalent, must be maintained by the provider agency for a minimum of three years. An entry shall be made on this form for each of the following situations:

- a. Change of shift.
- b. Any change to the narcotic inventory.
- c. Any time there is a change of responsible personnel

NOTE: Units authorized to participate in the 1:1 Staffing Program for Interfacility Transports are required to inventory controlled drugs at the end of the specified shift, when two paramedics are available to count and co-sign for the drugs.

5. Provider agencies that restock controlled drugs from County operated pharmacies shall forward copies of Reference No. 702.2, Monthly Controlled Drug Storage Inspection Form or its equivalent, to their assigned DHS pharmacy no later than the 30th of the following month.

F. Loss of Controlled Substances

1. Issued by a County Operated Pharmacy
- a. Any loss of controlled substances or discrepancy in the controlled drug count is to be reported by the following business day to the Department of Health (DHS) pharmacy that supplied the drugs. The follow up paperwork shall be submitted within five business days.
 - b. Any loss or discrepancy shall also be reported to the paramedic coordinator, the EMS Agency, and the Provider Agency Medical Director or other authorized physician.
 - c. Any loss of controlled substances shall be documented on Reference No. 702.1, Missing/Expired Controlled Drug Pharmacy Reporting Form, and shall initiate supervisory review at the involved provider agency. The original of the completed form will be presented to the DHS pharmacy that dispensed the drugs.
 - d. If a provider agency's internal investigation into a controlled drug loss exceeds thirty days, the provider shall submit a status update to the issuing DHS pharmacy and the EMS Agency at the 30th day.

2. Authorized by a Provider Agency Medical Director or Drug Authorizing Physician
 - a. Any loss or discrepancy shall be reported by the following business day to the paramedic coordinator, the EMS Agency, and the authorizing Provider Agency Medical Director or Drug Authorizing Physician.
 - b. Any significant loss, breakage or discrepancy in the count requires notification to the Drug Enforcement Administration, utilizing DEA Form 106 or electronically via the DEA web site, within one business day of discovery.
 - c. Any loss shall initiate supervisory review at the involved provider agency. If a provider agency's internal investigation into a controlled drug loss exceeds 30 days, the provider shall submit a status update to the Provider Agency Medical Director and the EMS Agency.

V. Record Keeping

- A. All controlled drugs issued to a provider agency must be accounted for. The provider agency shall retain a copy of the EMS Report Form (or an ePCR) for each patient to whom a controlled drug was administered and maintain it with any completed Missing/Expired Controlled Drug Reporting Forms, drug orders, invoices or other associated documentation in a separate file for a minimum of three years.
- B. Each controlled drug use must be documented on the EMS Report Form (or an ePCR). If the total amount of the drug is not administered, the remaining amount shall be wasted at the receiving facility. Wasted narcotics (partial or whole) must be documented in the "Narcotic Waste/Witness" section of the EMS Report Form or an ePCR, including the amount wasted and the witness at the receiving hospital's printed name and signature (registered nurse, physician, pharmacist).
- C. In addition to the local EMS Agency and the provider agency, controlled drug inventories and logs are subject to inspection by the issuing pharmacy, the California Board of Pharmacy, and agents of the Bureau of Narcotic Enforcement Administration of the Department of Justice, Federal Drug Enforcement Administration.

CROSS REFERENCES:

Prehospital Care Policy Manual:

- Reference No. 410. **Provider Agency Drug Authorizing Physician**
Reference No. 411. **Provider Agency Medical Director**
Reference No. 606. **Documentation of Prehospital Care**
Reference No. 701. **Supply and Resupply of Designated EMS Provider Units/Vehicles**
Reference No. 702.1. **Missing/Expired Controlled Drug Pharmacy Reporting Form**
Reference No. 702.2. **Daily Controlled Drug and Key Inventory Form (Page 1 of 2)**
Monthly Drug Storage Inspection Form (Page 2 of 2)
Reference No. 702.3. **County Operated Pharmacy Contact Numbers for Reporting Loss of Controlled Drugs**
Reference No. 702.4. **Provider Agency Medical Director Notification of Controlled Substance Program Implementation**

DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: MISSING/EXPIRED CONTROLLED DRUG
PHARMACY REPORTING FORM

Reference No. 702.1

1. Provider Agency _____ Unit number _____

2. Request for exchange of EXPIRED drugs:

Drug	# of syringes or equivalent	Strength	Total mg.
Midazolam			
Morphine Sulfate			

3. Request for replacement. Item is: (CIRCLE ONE) Missing/Broken

Drug	# of syringes or equivalent	Strength	Total mg.
Midazolam			
Morphine Sulfate			

4. Date and time narcotic and/or inventory form loss was discovered: __/__/__ @ __:__

5. Print name and title of individual(s) who discovered the narcotic or inventory form loss:

6. If missing, provide a brief description of the incident: _____

7. Print name/title of person completing this form _____

Signature _____ Date completed: __/__/__

8. Paramedic Coordinator's signature _____

FOR PHARMACY USE ONLY

Replaced: Midazolam # of syringes or equivalent: _____ Total mg: _____
Morphine Sulfate # of syringes or equivalent: _____ Total mg: _____

Pharmacist: _____ Date: _____ Time: _____

Lost narcotic number: _____

DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: MONTHLY DRUG STORAGE INSPECTION FORM

REFERENCE NO. 702.2

Provider Agency: _____ ALS Unit: _____

Date/Time Monthly Drug Storage Inspection Form conducted: _____

Verify the following items:	YES	NO
1. Controlled substances are adequately locked and secured.		
2. Expiration dates were verified. Indicate any expired medications: _____		
3. Controlled substance physical inventory count matches documentation.		
4. All forms are complete and legible including:		
a. RN printed name and signatures and clearly displayed.		
b. Paramedic signatures and license numbers clearly displayed.		
c. Name of drug and amount wasted clearly noted.		
Other Findings:		
Recommendations:		
Actions Taken:		
Comments:		
INSPECTOR'S NAME/TITLE:		
INSPECTOR'S SIGNATURE		

DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

REFERENCE NO. 702.3

SUBJECT: **COUNTY-OPERATED PHARMACY CONTACT
NUMBERS FOR REPORTING LOST CONTROLLED DRUGS**

Harbor-UCLA Medical Center
1000 W. Carson Street
Torrance, California 90502
Narcotic Pharmacist – (310) 222-2357

LAC + USC Medical Center
1200 N. State Street
Los Angeles, California 90033
Narcotic Pharmacist – (323) 226-6763

Olive View Medical Center
14445 Olive View Drive
Sylmar, California 91342
Monday – Friday: 8:00–16:30: (818) 364-3225
Narcotic Pharmacist – (818) 364-3059 or (818) 364-1555 Ext. 5956 or 6152

NOTE: Telephone reporting should be conducted during business hours.

DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: PROVIDER AGENCY MEDICAL DIRECTOR NOTIFICATION
OF CONTROLLED SUBSTANCE PROGRAM
IMPLEMENTATION

REFERENCE NO. 702.4

I _____ am a physician licensed by the State of California to practice medicine, and authorized by the U.S. Department of Justice - Drug Enforcement Administration to purchase schedule II - IV controlled substances. My DEA registration number is _____. I have current knowledge of all Federal, State and County Regulations governing controlled substance procurement and administration and will assume total responsibility for the controlled substance "program" at _____, Fire Department/Approved ALS Provider Agency, including but not limited to, procurement, storage, control, safeguards, recordkeeping, disposal, and inventory.

Physician

Signature

Printed Name

Date

Fire Chief/CEO/President

Signature

Printed Name

Date

EXHIBIT C

CONTROLLED SUBSTANCES INVENTORY

<u>Substance</u>	<u>Unit Dose</u>	<u>Maximum Quantity</u>
1. Morphine Sulfate	4 mg	60 mg
2. Midazolam (Versed®)	5 mg	40 mg

**CONTROLLED SUBSTANCES SUPPLY FOR PARAMEDIC
PROVIDER AGENCIES
FEE SCHEDULE**

CONTROLLED SUBSTANCE	DOSAGE	COST¹
Morphine Sulfate	4 mg unit	\$9
Midazolam (Versed®)	5 mg unit	\$9

¹Cost includes actual purchase price of the drug, plus additional incidental and administrative expenses incurred in procuring and dispensing the controlled substances.

EXPIRED CONTROLLED SUBSTANCES		
CONTROLLED SUBSTANCE	DOSAGE	INGREDIENT COST
Morphine Sulfate	4 mg unit	Actual Cost
Midazolam (Versed®)	5 mg unit	Actual Cost

RECALLED CONTROLLED SUBSTANCES	
Restocking Fee	\$9 Per Lot

OTHER	
Tampering/Diversion Testing Fee	Actual Cost
Board of Pharmacy Fines	Actual Cost

Above fees may be adjusted annually each July 1, as stated in Paragraph 5.0, Agreement Sum, of the Agreement.



155 North Wacker Drive
Chicago, Illinois 60606

312 775 4100 main
312 775 4580 fax

Novation[™]
The Supply Company of VHA & UHC

1. Application Type: Novation Affiliate Purchasing Program Agreement

An Affiliate is any entity that is sponsored by a UHC Member or Associate Member, and is making purchases independent of the UHC Member or Associate Member.

2. Identification

Name of Affiliate

Address of Affiliate

Main Phone

City

State

Zipcode

3. Primary Materials Management Contact at Affiliate

First and Last Name

Phone

Address (if different from section 2)

Fax

City

State

ZIP Code

E-mail

First and Last Name of Primary Pharmacy Contact

Phone

Address (if different from section 2)

Fax

City

State

ZIP Code

E-mail



155 North Wacker Drive
Chicago, Illinois 60606

312 775 4100 main
312 775 4580 fax

Novation
The Supply Company of VHA & UHC

4. Facility Type

Ambulatory Care Center/ Closed Rx <input type="checkbox"/> Ambulatory Care Center <input type="checkbox"/> Student Health Service <input type="checkbox"/> Oncology Center <input type="checkbox"/> Dialysis Center <input type="checkbox"/> Surgery Center <input type="checkbox"/> Dental <input type="checkbox"/> Diagnostic Imaging Center <input type="checkbox"/> Outpatient <input type="checkbox"/> Immediate Care Center	Home Health Care/ Closed Rx <input type="checkbox"/> Home Health Care <input type="checkbox"/> Home Infusion <input type="checkbox"/> Hospice <input type="checkbox"/> Durable Medical Equipment (non resaler) Physician/Practices Closed Rx <input type="checkbox"/> Clinical or Medical Group <input type="checkbox"/> Physician's Office	Long Term Care/ Closed Rx <input type="checkbox"/> Nursing Home <input type="checkbox"/> Retirement Center <input type="checkbox"/> Skilled Nursing Facility <input type="checkbox"/> Sub-Acute Facility <input type="checkbox"/> Assisted Living Managed Care Plan/ Closed Rx <input type="checkbox"/> Correctional Facility <input type="checkbox"/> University Campus <input type="checkbox"/> Other, please specify	Non Caregiving/Closed Rx <input type="checkbox"/> Fitness Center <input type="checkbox"/> Foundation <input type="checkbox"/> Laundry <input type="checkbox"/> Warehouse <input type="checkbox"/> Management Service Pharmacy <input type="checkbox"/> Pharmacy Closed <input type="checkbox"/> Pharmacy Retail <input type="checkbox"/> Pharmacy Retail & Closed
---	---	--	--

You can add additional or alternate shipping locations (ASLs) as part of this application. An ASL is an entity in which the Member makes purchases on behalf of the ASL. This includes warehouses and entities that send purchase orders to the Participant to purchase on their behalf.

To add additional shipping locations, attach spreadsheet containing the following information:

- Facility name, address (including city, state, zip), phone, fax
- Facility DEA number
- Facility Type (from section above)
- Material director/manager name, job title, phone, fax, email, and address (if different from facility address)
- Pharmacy director/manager name, job title, phone, fax, email, and address (if different from facility address)

5. Group Purchasing Participation Information

Participate in:

<input type="checkbox"/> Medical-Surgical & Pharmacy*	MedSurg Start Date	_____
	Pharmacy Start Date:	_____
<input type="checkbox"/> Capital Equipment	Start Date:	_____
<input type="checkbox"/> Purchased Services	Start Date:	_____

**For Pharmacy participation: DEA Number must be supplied in table below. Also requires the member to fill out a Pharmacy Program Participation Agreement.*

Standard Terms & Conditions may require 30-45 days notice to the suppliers to add a new participant to a purchasing agreement.



155 North Wacker Drive
Chicago, Illinois 60606

312 775 4100 main
312 775 4580 fax

Novation[™]
The Supply Company of VHA & UHC

6. Distribution Declaration

Distribution Declaration (Please indicate Start Date and select one or none from each category)		
<i>Acute distributors can be selected if this facility is owned/managed/controlled by sponsoring hospital.</i>		
Medical-Surgical Distribution (Acute) Start Date _____ <input type="checkbox"/> Cardinal Healthcare <input type="checkbox"/> Medline Industries <input type="checkbox"/> Owens & Minor <input type="checkbox"/> *American Medical Depot <input type="checkbox"/> *Buffalo Hospital Supply <input type="checkbox"/> *Clafin Company <input type="checkbox"/> *Kreiser Inc. <input type="checkbox"/> *Midland Medical Supply <input type="checkbox"/> *Midwest Medical Supply <input type="checkbox"/> *N.S. Low <input type="checkbox"/> *Professional Hospital Supply <input type="checkbox"/> *Seneca medical <input type="checkbox"/> *Shared Service Systems	Pharmaceutical Distribution (Acute) ** Start Date _____ DEA# _____ <input type="checkbox"/> Amerisource Bergen <input type="checkbox"/> Cardinal Drug <input type="checkbox"/> McKesson Drug <input type="checkbox"/> *Burlington Drug <input type="checkbox"/> *Morris & Dickson Pharmacy Distribution (Non-Acute) ** Start Date _____ DEA# _____ (may choose one from each group) <input type="checkbox"/> Cardinal Healthcare (P, A) <input type="checkbox"/> McKesson Corp. (P, A) <input type="checkbox"/> Physician Sales & Services (P, A) <input type="checkbox"/> Besse Medical (P, A, L, H, HP) <input type="checkbox"/> CuraScript (P, A, L, H, HP) <input type="checkbox"/> Seacoast Medical (P, A, L, H, HP) <input type="checkbox"/> *Kinray, Inc. (P, A, L, H, HP) Office Products Distribution Start Date _____ <input type="checkbox"/> OfficeMax <input type="checkbox"/> Corporate Express <small>Class of Trades: P=Physician, A=Ambulatory Care, L=LongTerm Care, H=Home Healthcare, HP=Home Healthcare Patient Specific * Regional - See individual launch packages for awarded states ** DEA # Required</small>	Laboratory Distribution Start Date _____ <input type="checkbox"/> Cardinal Healthcare Imaging Distribution Start Date _____ <input type="checkbox"/> Capital X-Ray <input type="checkbox"/> Evans-Sherratt Company <input type="checkbox"/> Jefferson Medical & Imaging, Inc. <input type="checkbox"/> Merry X-Ray Medical Enterprise, LLC <input type="checkbox"/> NHD, Inc. Food & Nutrition Distribution Start Date _____ <input type="checkbox"/> US Foodservice Maintenance, Repair, Operation Distribution Start Date _____ <input type="checkbox"/> Controlled Environmental Products <input type="checkbox"/> Grainger Industrial Supply <input type="checkbox"/> Graybar Electrical Co. Inc. Housekeeping Distribution Start Date _____ <input type="checkbox"/> AFFLINK <input type="checkbox"/> Network Services <input type="checkbox"/> Xpedx Dental Distribution Start Date _____ <input type="checkbox"/> American Dental Cooperative
Medical-Surgical Distribution (Non-Acute) Start Date _____ <input type="checkbox"/> Cardinal Healthcare (P, A) <input type="checkbox"/> McKesson Corp. (P, A) <input type="checkbox"/> Physician Sales & Services (P, A) <input type="checkbox"/> Gulf South Medical Supply (L, H, HP) <input type="checkbox"/> Medical Specialties (L, H, HP) <input type="checkbox"/> Independence Medical (L, H, HP) <input type="checkbox"/> Home Healthcare Solutions (HP) <input type="checkbox"/> *Activus (P, A, L) <input type="checkbox"/> *Kreisers Inc. (P, A, H) <input type="checkbox"/> *National Distribution & Contracting (P, A, L, H)		

The applications for the specific Novation distribution agreements referenced prior will be hand delivered by your Novation Service Delivery Account Executive.

As a participant of UHC, each participant is eligible to access UHC's contract solutions agreements. There is no additional participation fee for this service. By signing this application, you acknowledge your understanding of the following information as it pertains to access of contracts negotiated by UHC Contract Solutions, Novation, and/or the Academic Medical Research Center Purchasing Program.



155 North Wacker Drive
Chicago, Illinois 60606

312 775 4100 main
312 775 4580 fax

Novation
The Supply Company of VHA & UHC

7. Agreement

This section applies to each Affiliate that has elected to participate in UHC's Group Purchasing Program (through UHC Contract Solutions, Novation and the Academic Medical Research Center Purchasing Program) and is intended to maintain UHC and Novation's compliance with both the Medicare Anti-Kickback Statute's GPO Safe Harbor (42 CFR 1001.952(j)) and the Stark Law's GPO Exception (42 USC 1320-7b(3)(C)). By executing this purchasing profile form, Participant:

- Authorizes UHC (and its agents, including Novation) to act as a group purchasing organization (GPO) on behalf of the Affiliate.
- Understands and agrees that UHC will receive administrative fees ("Fees") from suppliers and distributors ("Vendors") based on Affiliate's purchases under UHC or Novation contracts ("Contracts") and may furnish certain administrative and promotional services to such Vendors.
- Understands and agrees that except as noted herein, each Contract provides for Fees that are fixed at three percent or less of the purchase price of the goods or services covered by the Contract; and that with respect to Contracts providing for Fees that are not so fixed, Affiliate:
 - (1) Will have access to a web-based report on the UHC Marketplace website indicating the Fees that UHC may receive from each Vendor under each such Contract ("Fee Report"); and
 - (2) Will have access to timely updates to the Fee Report ("Fee Report Updates") for all such Contracts that are executed after the Fee Report is generated.
- Understands and agrees that UHC shall provide the Affiliate's sponsoring Member with an annual report ("Sales and Revenue Report") listing: (1) Affiliate's purchases under each Contract; and (2) the Fees received from Vendors based on such purchases, unless sponsoring Member directs UHC otherwise in writing.
- Understands and agrees to a three (3) year term ("Initial Term") of participation in the UHC/Novation group purchasing program, which shall automatically extend for additional 1-year terms ("Renewal Terms"), unless Affiliate provides UHC ninety (90) days Notice of Termination from the group purchasing program.
- Understands that the Fee Report, the Annual Sales and Revenue Report and all Fee Report Updates shall be automatically incorporated herein by reference. If Affiliate is considering purchasing under a Contract that is not listed on the Fee Report or a Fee Report Update, or if Affiliate otherwise needs any Fee or other information relating to any Contract, Affiliate may contact UHC's Vice President of Finance at 630/954-1700.

Affiliate hereby authorizes UHC to send the Fee Report, all Fee Report Updates, and all annual Sales and Revenue Reports to Affiliate's Chief Financial Officer.

Please note that to the extent Affiliate receives or earns discounts, rebates, incentives or any other price reductions (such as manufacturer incentives or patronage dividends) as a result of purchases made under UHC's Group Purchasing Program, Affiliate may have an obligation to disclose such price reductions (as part of the cost reporting process, for example) to federal or state health care programs or other payers.

Affiliate understands and agrees to keep strictly confidential all UHC/Novation trade secrets, proprietary and other Confidential Information (especially pricing schedules), and shall not disclose such Confidential Information to any third party, and shall not use the Confidential Information for



155 North Wacker Drive
Chicago, Illinois 60606

312 775 4100 main
312 775 4580 fax

Novation[™]
The Supply Company of VHA & UHC

any purpose other than group purchasing through UHC/Novation, without the prior written consent of Novation and UHC. "Confidential Information" includes, but is not limited to: the information of UHC, its member organizations ("Members"), or Novation, LLC, ("Novation"), encompassed in all technology, plans, designs, concepts, financial information, costs, pricing, spend and fee data, computer programs, contract portfolios, videos, animation and designs; computer codes, including but not limited to, .NET, ASP, HTML, SQL, JAVA or JavaScript; formulas, websites, including UHC Marketplace, and equations; databases; customer information, vendors, business partners or suppliers; business and marketing plans or strategies; financial performance and projections; and all concepts, know-how, or ideas in or directly related to UHC's business, the business of its Members, and the business of Novation that have not previously been publicly released by duly authorized representatives of UHC, its Members, or Novation.

UHC has instituted corporate policies and procedures for the business operations of its group purchasing business. Such policies may be updated from time to time and are hereby incorporated herein by reference. Affiliate acknowledges and agrees that it shall comply with all such policies, including but not limited to the Notice of Termination requirement, as well as those policies detailing certain consequences for an Affiliate who terminates participation in the UHC/Novation purchasing program. Contact the UHC Senior Vice President of Supply Chain for UHC's current policies at 630.954.1700.

I verify that, to the best of my knowledge, the above listed organization purchases pharmaceuticals within the meaning of the Nonprofit Institutions Act (NIA) as interpreted by the U.S. Supreme Court in Abbott Laboratories vs. Portland Retail Druggist Association, Inc., 425 U.S. 1 (1976).

Information submitted by:

Name

Authorized Signature

Title

Date

Name of Sponsoring Member or Associate Member

Sponsor First Name

Sponsor Last Name

Sponsor Title

Sponsor Phone

Sponsor Fax

Sponsor Email

Sponsor Signature

Date



155 North Wacker Drive
Chicago, Illinois 60606

312 775 4100 main
312 775 4580 fax

Novation[™]
The Supply Company of VHA & UHC

8. Mailing / Fax Instructions

Please return completed form to:

Christine Santos, Membership Specialist

UHC

155 North Wacker Drive

Chicago, Illinois 60606

Phone: (312) 775-4320

Fax: (312) 775-4580

**CONTRACT FOR
CONTROLLED SUBSTANCES SUPPLY FOR PARAMEDIC PROVIDER AGENCIES**

TABLE OF CONTENTS OF EXHIBITS

STANDARD EXHIBITS

- A STATEMENT OF WORK
- B PREHOSPITAL CARE POLICY MANUAL (REFERENCE NO. 702)
- C CONTROLLED SUBSTANCES INVENTORY
- C-1 CONTROLLED SUBSTANCES PRICING SCHEDULE
- D PROVIDER'S EEO CERTIFICATION (Intentionally Omitted)
- E COUNTY'S ADMINISTRATION
- F PROVIDER'S ADMINISTRATION
- G-1 PROVIDER ACKNOWLEDGEMENT AND CONFIDENTIALITY AGREEMENT
- H JURY SERVICE ORDINANCE (Intentionally Omitted)
- I SAFELY SURRENDERED BABY LAW (Intentionally Omitted)

UNIQUE EXHIBITS

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AGREEMENT

- J PROVIDER'S OBLIGATIONS AS A "BUSINESS ASSOCIATE" UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) AND THE HEALTH INFORMATION AND TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (HITECH)
-

PROVIDER'S EEO CERTIFICATION

INTENTIONALLY OMITTED

COUNTY'S ADMINISTRATION

CONTRACT NO. _____

COUNTY PROJECT DIRECTOR:

Name: _____

Title: _____

Address: _____

Telephone: _____ Facsimile: _____

E-Mail Address: _____

COUNTY PROJECT MANAGER:

Name: _____

Title: _____

Address: _____

Telephone: _____ Facsimile: _____

E-Mail Address: _____

COUNTY CONTRACT PROJECT MONITOR:

Name: _____

Title: _____

Address: _____

Telephone: _____ Facsimile: _____

E-Mail Address: _____

PROVIDER'S ADMINISTRATION**PROVIDER'S NAME:** _____**CONTRACT NO:** _____**PROVIDER'S PROJECT MANAGER:**

Name: _____

Title: _____

Address: _____

Telephone: _____

Facsimile: _____

E-Mail Address: _____

PROVIDER'S AUTHORIZED OFFICIAL(S)

Name: _____

Title: _____

Address: _____

Telephone: _____

Facsimile: _____

E-Mail Address: _____

Name: _____

Title: _____

Address: _____

Telephone: _____

Facsimile: _____

E-Mail Address: _____

Notices to Provider shall be sent to the following:

Name: _____

Title: _____

Address: _____

Telephone: _____

Facsimile: _____

E-Mail Address: _____

PROVIDER ACKNOWLEDGEMENT AND CONFIDENTIALITY AGREEMENT

PROVIDER NAME _____ Contract No. _____

GENERAL INFORMATION:

The Provider referenced above has entered into a contract with the County of Los Angeles to provide certain services to the County. The County requires the Corporation to sign this Provider Acknowledgement and Confidentiality Agreement.

PROVIDER ACKNOWLEDGEMENT:

Provider understands and agrees that the Provider employees, consultants, Outsourced Vendors and independent providers (Provider's Staff) that will provide services in the above referenced agreement are Provider's sole responsibility. Provider understands and agrees that Provider's Staff must rely exclusively upon Provider for payment of salary and any and all other benefits payable by virtue of Provider's Staff's performance of work under the above-referenced contract.

Provider understands and agrees that Provider's Staff are not employees of the County of Los Angeles for any purpose whatsoever and that Provider's Staff do not have and will not acquire any rights or benefits of any kind from the County of Los Angeles by virtue of my performance of work under the above-referenced contract. Provider understands and agrees that Provider's Staff will not acquire any rights or benefits from the County of Los Angeles pursuant to any agreement between any person or entity and the County of Los Angeles.

CONFIDENTIALITY AGREEMENT:

Provider and Provider's Staff may be involved with work pertaining to services provided by the County of Los Angeles and, if so, Provider and Provider's Staff may have access to confidential data and information pertaining to persons and/or entities receiving services from the County. In addition, Provider and Provider's Staff may also have access to proprietary information supplied by other vendors doing business with the County of Los Angeles. The County has a legal obligation to protect all such confidential data and information in its possession, especially data and information concerning health, criminal, and welfare recipient records. Provider and Provider's Staff understand that if they are involved in County work, the County must ensure that Provider and Provider's Staff, will protect the confidentiality of such data and information. Consequently, Provider must sign this Confidentiality Agreement as a condition of work to be provided by Provider's Staff for the County.

Provider and Provider's Staff hereby agrees that they will not divulge to any unauthorized person any data or information obtained while performing work pursuant to the above-referenced contract between Provider and the County of Los Angeles. Provider and Provider's Staff agree to forward all requests for the release of any data or information received to County's Project Manager.

Provider and Provider's Staff agree to keep confidential all health, criminal, and welfare recipient records and all data and information pertaining to persons and/or entities receiving services from the County, design concepts, algorithms, programs, formats, documentation, Provider proprietary information and all other original materials produced, created, or provided to Provider and Provider's Staff under the above-referenced contract. Provider and Provider's Staff agree to protect these confidential materials against disclosure to other than Provider or County employees who have a need to know the information. Provider and Provider's Staff agree that if proprietary information supplied by other County vendors is provided to me during this employment, Provider and Provider's Staff shall keep such information confidential.

Provider and Provider's Staff agree to report any and all violations of this agreement by Provider and Provider's Staff and/or by any other person of whom Provider and Provider's Staff become aware.

Provider and Provider's Staff acknowledge that violation of this agreement may subject Provider and Provider's Staff to civil and/or criminal action and that the County of Los Angeles may seek all possible legal redress.

SIGNATURE: _____

DATE: ____/____/____

PRINTED NAME: _____

POSITION: _____

JURY SERVICE ORDINANCE

INTENTIONALLY OMITTED

SAFELY SURRENDERED BABY LAW

INTENTIONALLY OMITTED

**AGREEMENT
PROVIDER'S OBLIGATIONS AS A
"BUSINESS ASSOCIATE" UNDER THE HEALTH INSURANCE
PORTABILITY AND ACCOUNTABILITY ACT OF 1996
AND THE HEALTH CARE INFORMATION TECHNOLOGY
FOR ECONOMIC AND CLINICAL HEALTH ACT
(BUSINESS ASSOCIATE AGREEMENT)**

Under this Agreement, Provider ("Business Associate") provides services ("Services") to County ("Covered Entity") and Business Associate receives, has access to or creates Protected Health Information in order to provide those Services.

Covered Entity is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), and regulations promulgated thereunder, including the Standards for Privacy of Individually Identifiable Health Information ("Privacy Regulations") and the Health Insurance Reform: Security Standards ("the Security Regulations") at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164 (together, the "Privacy and Security Regulations"). The Privacy and Security Regulations require Covered Entity to enter into a contract with Business Associate ("Business Associate Agreement") in order to mandate certain protections for the privacy and security of Protected Health Information, and those Regulations prohibit the disclosure to or use of Protected Health Information by Business Associate if such a contract is not in place.

Further, pursuant to the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005, *title XIII and title IV of Division B*, ("HITECH Act"), effective February 17, 2010, certain provisions of the HIPAA Privacy and Security Regulations apply to Business Associates in the same manner as they apply to Covered Entity and such provisions must be incorporated into the Business Associate Agreement.

This Business Associate Agreement and the following provisions are intended to protect the privacy and provide for the security of Protected Health Information disclosed to or used by Business Associate in compliance with HIPAA's Privacy and Security Regulations and the HITECH Act, as they now exist or may hereafter be amended.

Therefore, the parties agree as follows:

DEFINITIONS

- 1.1 "Breach" has the same meaning as the term "breach" in 45 C.F.R. § 164.402.
 - 1.2 "Disclose" and "Disclosure" mean, with respect to Protected Health Information, the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information outside Business Associate's internal operations or to other than its employees.
-

- 1.3 "Electronic Health Record" has the same meaning as the term "electronic health record" in the HITECH Act, 42 U.S.C. section 17921. Electronic Health Record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.
- 1.4 "Electronic Media" has the same meaning as the term "electronic media" in 45 C.F.R. § 160.103. Electronic Media means (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission. The term "Electronic Media" draws no distinction between internal and external data, at rest (that is, in storage) as well as during transmission.
- 1.5 "Electronic Protected Health Information" has the same meaning as the term "electronic protected health information" in 45 C.F.R. § 160.103. Electronic Protected Health Information means Protected Health Information that is (i) transmitted by electronic media; (ii) maintained in electronic media.
- 1.6 "Individual" means the person who is the subject of Protected Health Information and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
- 1.7 "Minimum Necessary" refers to the minimum necessary standard in 45 C.F.R. § 162.502 (b) as in effect or as amended.
- 1.8 "Privacy Rule" means the Standards for Privacy of Individually Identifiable Health Information at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164, also referred to as the Privacy Regulations.
- 1.9 "Protected Health Information" has the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity. Protected Health Information includes information that (i) relates to the past, present or future physical or mental health or condition of an Individual; the provision of health care to an Individual, or the past, present or future payment for the provision of health care to an Individual; (ii) identifies the Individual (or for which
-

there is a reasonable basis for believing that the information can be used to identify the Individual); and (iii) is received by Business Associate from or on behalf of Covered Entity, or is created by Business Associate, or is made accessible to Business Associate by Covered Entity. "Protected Health Information" includes Electronic Health Information.

- 1.10 "Required By Law" means a mandate contained in law that compels an entity to make a Use or Disclosure of Protected Health Information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or any administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing benefits.
- 1.11 "Security Incident" means the attempted or successful unauthorized access, Use, Disclosure, modification, or destruction of information in, or interference with system operations of, an Information System which contains Electronic Protected Health Information. However, Security Incident does not include attempts to access an Information System when those attempts are not reasonably considered by Business Associate to constitute an actual threat to the Information System.
- 1.12 "Security Rule" means the Security Standards for the Protection of Electronic Health Information also referred to as the Security Regulations at 45 Code of Federal Regulations (C.F.R.) Part 160 and 164.
- 1.13 "Services" has the same meaning as in the body of this Agreement.
- 1.14 "Unsecured Protected Health Information" has the same meaning as the term "unsecured protected health information" in 45 C.F.R. § 164.402.
- 1.15 "Use" or "Uses" mean, with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Information within Business Associate's internal operations.
- 1.16 Terms used, but not otherwise defined in this Business Associate Agreement shall have the same meaning as those terms in the HIPAA Regulations and HITECH Act.

OBLIGATIONS OF BUSINESS ASSOCIATE

- 2.1 Permitted Uses and Disclosures of Protected Health Information. Business Associate:
-

(a) shall Use and Disclose Protected Health Information only as necessary to perform the Services, and as provided in Sections 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 4.3 and 5.2 of this Agreement;

(b) shall Disclose Protected Health Information to Covered Entity upon request;

(c) may, as necessary for the proper management and administration of its business or to carry out its legal responsibilities:

(i) Use Protected Health Information; and

(ii) Disclose Protected Health Information if the Disclosure is Required by Law.

Business Associate shall not Use or Disclose Protected Health Information for any other purpose or in any manner that would constitute a violation of the Privacy Regulations or the HITECH Act if so Used or Disclosed by Covered Entity.

2.2 Prohibited Uses and Disclosures of Protected Health Information. Business Associate:

(a) shall not Use or Disclose Protected Health Information for fundraising or marketing purposes.

(b) shall not disclose Protected Health Information to a health plan for payment or health care services that relate to the health plan.

(c) shall not directly or indirectly receive payment in exchange for Protected Health Information, except with the prior written consent of Covered Entity and as permitted by the HITECH Act. This prohibition shall not affect payment by Covered Entity to Business Associate. Covered Entity shall not provide such written consent except upon express approval of the departmental privacy officer and only to the extent permitted by law, including HIPAA and the HITECH Act.

2.3 Adequate Safeguards for Protected Health Information. Business Associate:

(a) shall implement and maintain appropriate safeguards to prevent the Use or Disclosure of Protected Health Information in any manner other than as permitted by this Business Associate Agreement. Business Associate agrees to limit the Use and Disclosure of Protected Health Information to the Minimum Necessary in accordance with the Privacy Regulation's minimum necessary standard as in effect or as amended.

- (b) as to Electronic Protected Health Information, shall implement and maintain administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information; effective February 17, 2010, said safeguards shall be in accordance with 45 C.F.R. Sections 164.308, 164.310, and 164.312, and shall comply with the Security Rule's policies and procedure and documentation requirements.

2.4 Reporting Non-Permitted Use or Disclosure and Security Incidents and Breaches of Unsecured Protected Health Information. Business Associate

- (a) shall report to Covered Entity each Use or Disclosure of Protected Health Information that is made by Business Associate, its employees, representatives, Agents, subcontractors, or other parties under Business Associate's control with access to Protected Health Information but which is not specifically permitted by this Business Associate Agreement or otherwise required by law.
- (b) shall report to Covered Entity each Security Incident of which Business Associate becomes aware.
- (c) shall notify Covered Entity of each Breach by Business Associate, its employees, representatives, agents or subcontractors of Unsecured Protected Health Information that is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate. Business Associate shall be deemed to have knowledge of a Breach of Unsecured Protected Health Information if the Breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the Breach, who is an employee, officer, or other agent of the Business Associate as determined in accordance with the federal common law of agency.

2.4.1 Immediate Telephonic Report. Except as provided in Section 2.4.3, notification shall be made immediately upon discovery of the non-permitted Use or Disclosure of Protected Health Information, Security Incident or Breach of Unsecured Protected Health Information by telephone call to [To Be Determined], telephone number 1(800) XXX-XXXX.

2.4.2 Written Report. Except as provided in Section 2.4.3, the initial telephonic notification shall be followed by written notification made without unreasonable delay and in no event later than three (3) business days from the date of discovery of the non-permitted Use or Disclosure of Protected Health Information, Security Incident, or Breach by the Business Associate to the Chief Privacy Officer at:

Chief Privacy Officer
Kenneth Hahn Hall of Administration
500 West Temple Street
Suite 525
Los Angeles, California 90012
HIPAA@auditor.lacounty.gov
(213) 974-2166

- (a) The notification required by section 2.4 shall include, to the extent possible, the identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, Used, or Disclosed; and
- (b) The notification required by section 2.4 shall include, to the extent possible, all information required to provide notification to the Individual under 45 C.F.R. 164.404(c), including:
 - (i) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - (ii) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
 - (iii) Any other details necessary to conduct an assessment of whether there is a risk of harm to the Individual;
 - (iv) Any steps Business Associate believes that the Individual could take to protect him or herself from potential harm resulting from the breach;
 - (v) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to the Individual, and to protect against any further Breaches; and
 - (vi) The name and contact information for the person most knowledge regarding the facts and circumstances of the Breach.

If Business Associate is not able to provide the information specified in section 2.3.2 (a) or (b) at the time of the notification required by section 2.4.2, Business Associate

shall provide such information promptly thereafter as such information becomes available.

- 2.4.3 Request for Delay by Law Enforcement. Business Associate may delay the notification required by section 2.4 if a law enforcement official states to Business Associate that notification would impede a criminal investigation or cause damage to national security. If the law enforcement official's statement is in writing and specifies the time for which a delay is required, Business Associate shall delay notification, notice, or posting for the time period specified by the official; if the statement is made orally, Business Associate shall document the statement, including the identity of the official making the statement, and delay notification, notice, or posting temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in paragraph (a) of this section is submitted during that time.
- 2.5 Mitigation of Harmful Effect. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this Business Associate Agreement.
- 2.6 Breach Notification. Business Associate shall, to the extent Covered Entity determines that there has been a Breach of Unsecured Protected Health Information, provide Breach notification for each and every Breach of Unsecured Protected Health Information by Business Associate, its employees, representatives, agents or subcontractors, in a manner that permits Covered Entity to comply with its obligations under Subpart D, Notification in the Case of Breach of Unsecured PHI, of the Privacy and Security Regulations, including:
- (a) Notifying each Individual whose Unsecured Protected Health Information has been, or is reasonably believed to have been, accessed, acquired, Used, or Disclosed as a result of such Breach;
 - (b) The notification required by paragraph (a) of this Section 2.6 shall include, to the extent possible:
 - (i) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - (ii) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
 - (iii) Any steps the Individual should take to protect him or herself from potential harm resulting from the Breach;
-

- (iv) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to individuals, and to protect against any further Breaches; and
- (v) Contact procedures for Individual(s) to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.
- (vi) The notification required by paragraph (a) of this section shall be written in plain language

Covered Entity, in its sole discretion, may elect to provide the notification required by this Section 2.6, and Business Associate shall reimburse Covered Entity any and all costs incurred by Covered Entity, including costs of notification, internet posting, or media publication, as a result of Business Associate's Breach of Unsecured Protected Health Information.

- 2.7 Availability of Internal Practices, Books and Records to Government Agencies. Business Associate agrees to make its internal practices, books and records relating to the Use and Disclosure of Protected Health Information available to the Secretary of the federal Department of Health and Human Services for purposes of determining Covered Entity's compliance with the Privacy and Security Regulations. Business Associate shall immediately notify Covered Entity of any requests made by the Secretary and provide Covered Entity with copies of any documents produced in response to such request.
- 2.8 Access to Protected Health Information. Business Associate shall, to the extent Covered Entity determines that any Protected Health Information constitutes a "designated record set" as defined by 45 C.F.R. § 164.501, make the Protected Health Information specified by Covered Entity available to the Individual(s) identified by Covered Entity as being entitled to access and copy that Protected Health Information. Business Associate shall provide such access for inspection of that Protected Health Information within two (2) business days after receipt of request from Covered Entity. Business Associate shall provide copies of that Protected Health Information within five (5) business days after receipt of request from Covered Entity. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act.
- 2.9 Amendment of Protected Health Information. Business Associate shall, to the extent Covered Entity determines that any Protected Health Information constitutes a "designated record set" as defined by 45 C.F.R. § 164.501, make any amendments to Protected Health Information that are requested by Covered Entity. Business Associate shall make such amendment within ten (10) business
-

days after receipt of request from Covered Entity in order for Covered Entity to meet the requirements under 45 C.F.R. § 164.526.

- 2.10 Accounting of Disclosures. Upon Covered Entity's request, Business Associate shall provide to Covered Entity an accounting of each Disclosure of Protected Health Information made by Business Associate or its employees, agents, representatives or subcontractors, in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528 and/or the HITECH Act which requires an Accounting of Disclosures of Protected Health Information maintained in an Electronic Health Record for treatment, payment, and health care operations.

[Optional, to be used when all Uses and Disclosures permitted in order to perform the Services will be for the Covered Entity's payment or health care operations activities: However, Business Associate is not required to provide an Accounting of Disclosures that are necessary to perform the Services because such Disclosures are for either payment or health care operations purposes, or both.]

Any accounting provided by Business Associate under this Section 2.10 shall include: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the Protected Health Information; (c) a brief description of the Protected Health Information disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that could require an accounting under this Section 2.10, Business Associate shall document the information specified in (a) through (d), above, and shall securely maintain the information for six (6) years from the date of the Disclosure. Business Associate shall provide to Covered Entity, within ten (10) business days after receipt of request from Covered Entity, information collected in accordance with this Section 2.10 to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act.

- 2.11 Indemnification. Business Associate shall indemnify, defend, and hold harmless Covered Entity, including its elected and appointed officers, employees, and agents, from and against any and all liability, including but not limited to demands, claims, actions, fees, costs, penalties and fines (including regulatory penalties and/or fines), and expenses (including attorney and expert witness fees), arising from or connected with Business Associate's acts and/or omissions arising from and/or relating to this Business Associate Agreement; Business Associate's obligations under this provision extend to compliance and/or enforcement actions and/or activities, whether formal or informal, of Secretary of
-

the federal Department of Health and Human Services and/or Office for Civil Rights.

3.0 OBLIGATION OF COVERED ENTITY

- 3.1 Obligation of Covered Entity. Covered Entity shall notify Business Associate of any current or future restrictions or limitations on the use of Protected Health Information that would affect Business Associate's performance of the Services, and Business Associate shall thereafter restrict or limit its own uses and disclosures accordingly.

4.0 TERM AND TERMINATION

- 4.1 Term. The term of this Business Associate Agreement shall be the same as the term of this Agreement. Business Associate's obligations under Sections 2.1 (as modified by Section 4.2), 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 4.3 and 5.2 shall survive the termination or expiration of this Agreement.

- 4.2 Termination for Cause. In addition to and notwithstanding the termination provisions set forth in this Agreement, upon either party's knowledge of a material breach by the other party, the party with knowledge of the other party's breach shall:

- (a) Provide an opportunity for the breaching party to cure the breach or end the violation and terminate this Agreement if the breaching party does not cure the breach or end the violation within the time specified by the non-breaching party;
- (b) Immediately terminate this Agreement if a party has breached a material term of this Agreement and cure is not possible; or
- (c) If neither termination nor cure is feasible, report the violation to the Secretary of the federal Department of Health and Human Services.

- 4.3 Disposition of Protected Health Information Upon Termination or Expiration.

- (a) Except as provided in paragraph (b) of this section, upon termination for any reason or expiration of this Agreement, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
 - (b) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall
-

provide to Covered Entity notification of the conditions that make infeasible. If return or destruction is infeasible, Business Associate shall extend the protections of this Business Associate Agreement to such Protected Health Information and limit further Uses and Disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

5.0 MISCELLANEOUS

- 5.1 No Third Party Beneficiaries. Nothing in this Business Associate Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
 - 5.2 Use of Subcontractors and Agents. Business Associate shall require each of its agents and subcontractors that receive Protected Health Information from Business Associate, or create Protected Health Information for Business Associate, on behalf of Covered Entity, to execute a written agreement obligating the agent or subcontractor to comply with all the terms of this Business Associate Agreement.
 - 5.3 Relationship to Services Agreement Provisions. In the event that a provision of this Business Associate Agreement is contrary to another provision of this Agreement, the provision of this Business Associate Agreement shall control. Otherwise, this Business Associate Agreement shall be construed under, and in accordance with, the terms of this Agreement.
 - 5.4 Regulatory References. A reference in this Business Associate Agreement to a section in the Privacy or Security Regulations means the section as in effect or as amended.
 - 5.5 Interpretation. Any ambiguity in this Business Associate Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy and Security Regulations.
 - 5.6 Amendment. The parties agree to take such action as is necessary to amend this Business Associate Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy and Security Regulations and other privacy laws governing Protected Health Information
-