Glossary of Terms

As used in this document, unless otherwise provided or the context otherwise requires, the following definitions of terms will govern the construction of this document:

Administrative Bulletin	Bulletins released to all potential Applicants who have submitted Mandatory Letters of Intent and may include addenda and/or additional information and/or data.
Applicant	A sole proprietorship, firm, partnership, corporation, or any other business venture that responds to an RFA by submitting a response to the contracting agency.
Application	The term used synonymously with the RFA response. A potential Contractor's presentation of proposed activities and/or actions, including recommended approaches or methods to solve or meet a service need, submitted in response to the RFA issued by the State.
Attachments	Unique materials relating to the contract and incorporated by reference.
Attestation of Understanding/Agreement	A Contractor's formal declaration of the terms requested and required by the RFA.
Attorney General	The name commonly used to refer to any of the deputies on the staff of the Office of the Attorney General of the State of California.
Beneficiary	A person who is determined eligible for the Medi-Cal or other special health care (non-managed care) programs.
Biller (Billing Agent, Third Party Billing Agent)	"Biller" includes any employee, officer, agent or director of the entity, which will bill on behalf of a contractor pursuant to a contractual relationship with the contractor, which does not include payment to billers on the basis of a percentage of amount billed or collected from Medi-Cal (Title 22, California Code of Regulations, Section 51502.1, Requirements for Electronic Claims Submission (a)(1)).
Carrier	Any insurer, including private company, corporation, mutual association, trust fund, reciprocal or inter-insurance exchange authorized under the laws of California to insure persons against liability or injuries caused by another.

Clinical Laboratory or Laboratory	"Clinical Laboratory" or "Laboratory" means any place used, organized, or operated, for the examination, detection, identification, measurement, or enumeration of any particular entity or substance, which consists of materials derived from the human body for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being (Title 22, California Code of Regulations, Section 51137).
Clinical Laboratory Improvement Amendments (CLIA)	For purposes of this chapter, "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; P.L. 100-578) and the regulations adopted thereunder by the Centers for Medicare and Medicaid Services (CMS) and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208.
Contract	A legally binding agreement between the State and another entity, public or private, for the provision of goods or services.
Contract Effective Date	The date upon which the terms of the contract go into effect. The date is specified in the contract on the standard contract form.
Contract Requirement/Deliverable	Any service, deliverable or other duty that the Contractor is required to provide or perform under the terms of the contract.
Contract Term	Used to identify the starting and ending date of the contract and/or the time allowed for the performance and completion of the contract.
Contractor	The individual, company, public entity, or organization that has been awarded a contract.
Current Procedural Terminology, Fourth Edition 2003 (CPT® Code/ CPT-4 Code)	2003 American Medical Association list of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians. Commonly referred to as CPT.
Data	Facts, or a collection of facts, used to make a judgment.

Department of Health Services (DHS)	The single State agency responsible for administration of Medi-Cal, Medi-Cal Managed Care, County Medical Services, California Children Services, and other related programs.
Department Representative	An individual assigned by the Director to act in the Department's interest.
Fee-For-Service (FFS)	A method of charging the Medi-Cal program for specific services provided to an eligible Beneficiary.
Letter of Intent (Mandatory)	A letter sent to the State by a potential Applicant notifying DHS of the Applicant's intention to participate in the RFA process..
Licensed Practitioner	This individual is legally authorized within the scope of practice as defined by California law to order clinical laboratory tests or examinations for the purpose of providing information for diagnosis, prevention, or treatment of any disease, injury or impairment of, or the assessment of the health of human beings, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition or illness in a human being (Title 22, California Code of Regulations, Section 51311(a)).
Medicaid (Title XIX)	The program authorized by Title XIX of the Social Security Act to provide medical benefits for certain low-income persons.
Medi-Cal Program	Medicaid Program administered by the State of California per Title XIX Federal Medical Assistance Program to provide Federal and State financial assistance for the health and medical care of needy persons meeting program eligibility requirements.
Medicare (Title XVIII)	The program authorized by Title XVIII of the Social Security Act of 1965 to provide payment for health services to the population aged 65 and over.
Non-Solo Practitioner	A clinical laboratory performing clinical laboratory tests or examinations on Beneficiaries that have been referred to the clinical laboratory.
Office of Medi-Cal Procurement (OMCP)	The office responsible for all DHS Medi-Cal related procurements.
Proprietary	Ownership such as held under patent, trademark, or copyright. The term can include information (contract data) which is unique to a company and which, in the hands of a competitor, would be detrimental to the company.

Provider	Any individual, partnership, provider group, association, corporation, institution, or entity, and the officers, directors, employees, or agents thereof, that provides services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary, that meets the Standards for Participation specified in Article 3 (commencing with Section 51200), and that has been enrolled in the Medi-Cal program (Title 22, California Code of Regulations, Sections 51000.1 through 51000.55 and 51051).
Redacted Application	A application that has been selected or adapted for publication. For purposes of this RFA, this is a copy of the application that has been edited by blackening out personal information and corporate proprietary information so that the public may not view these items.
Request for Application (RFA)	The solicitation document that describes the qualification requirements, performance specifications, time frame, and other requirements and asks the applicants to describe how they would accomplish the contract objectives.
Sanctioned	Individual who has been subjected to any suspension, whether temporary or not, any withhold of payments or the imposition of any fines or penalties.
Scope of Work	Work activities, actions to be performed, deliverables to be supplied, methods and approaches to be used, and expected objectives and outcomes to be achieved under a contractual agreement.
Solo Practitioner	One physician performing clinical laboratory tests or examinations on only his/her own patients.
Third Party Payor	A third party payor is the entity that pays for services provided to a Beneficiary.
Title XVIII	The Title of the Social Security Act that authorizes the Medicare program.
Title XIX	The Title of the Social Security Act that enacted Medicaid in 1965.
Title 22	Title 22, Division 3, California Code of Regulations contains the rules and regulations governing the Medi-Cal program. These regulations define and clarify the provisions of the State statute, primarily the Welfare and Institutions Code.

Welfare and Institutions Code	The California code that includes the laws that govern the Medi-Cal Program.
World Health Organization's Ninth Revision, International Classification of Diseases Clinical Modification (ICD-9/ICD-9-CM)	ICD-9-CM is the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States and is used to code and classify morbidity data from the inpatient and outpatient records, physician offices, and most National Center for Health Statistics (NCHS) surveys. Commonly referred to as ICD-9.

Title 22, California Code of Regulations, Section 51000.3, Business Address

"Business address" means the place at which the applicant or provider shall render health care services, or provide goods, supplies, or merchandise, to Medi-Cal beneficiaries. The business address shall include the street name and number, room or suite number or letter, city, county, state and 9-digit zip code. A post office box, commercial box, vehicle, or vessel is not a business address.

Title 22, California Code of Regulations, Section 51000.40, Medi-Cal Supplemental Application Requirements

A provider, including a provider group, shall complete the "Medi-Cal Supplemental Application," DHS 6209, (Rev. 12/00), incorporated by reference herein, to inform the Department within 35 days of any change in information previously submitted to the Department as required pursuant to Section 51000.30(b), to add or change the following information, or to request the following actions:

(a) Change of business address, except for providers of incontinence medical supplies and for a pharmacy.
(b) Business telephone number.
(c) Pharmacist-in-charge, if the provider is a pharmacy.
(d) Medicare billing number.
(e) Business activities, if the provider currently provides durable medical equipment and/or incontinence medical supplies and:
  (1) The change requires the issuance of a new license, permit, or certificate; or
  (2) The provider is adding or deleting incontinence medical supplies.
(f) Tax identification number.
(g) Name under which the provider or provider group is doing business (DBA).
(h) CLIA number.
(i) Deactivation of a provider number or a group provider number.
(j) Re-issuance of a Provider Identification Number (PIN).
(k) For providers of medical transportation services:
  (1) Vehicle or aircraft information.
  (2) Driver or pilot information, or the addition of information on a new driver or pilot.
  (3) The days and/or hours of operation of the applicant's or provider's business.
  (4) The geographic area(s) served.
(l) Deletion of a rendering provider from a provider group.
(m) A change of less than 50 percent in the ownership or control interest, as defined in Section 51000.15, of the provider, or provider group.

Title 22, California Code of Regulations, Section 51200, Basic Requirements for Program Participation

(a) In addition to any other statutory or regulatory conditions for participation in the Medi-Cal program and any federal requirements for participation in Medicaid, as a condition for enrollment, or continued enrollment, an applicant or provider also shall meet the standards specified in this Article, applicable to their provider type, and the requirements specified in Sections 51000.30 through 51000.55. Failure to meet applicable standards for participation shall result in the denial of the applicant's or provider's application for enrollment, or continued enrollment, as specified in Section 51000.50.

(b) Any provider who violates any provision of law or regulation that governs the Medi-Cal program shall be subject to temporary or permanent suspension from the Medi-Cal program, as permitted by Section 14123, Welfare and Institutions (W&I) Code

(c) All providers shall be subject to temporary suspension, including temporary deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program, under any of the following circumstances:

(1) The provider has failed to disclose all information required in federal Medicaid regulations or any other information required by the Department, or has disclosed false information, as specified in Section 14043.2, W&I Code.

(2) The provider is discovered to be under investigation for fraud or abuse, as specified in Section 14043.36.

(3) The provider has failed to remediate discrepancies that are discovered as a result of an unannounced visit to the provider, as specified in Section 14043.7, W&I Code.

(d) All applicants applying for enrollment, or providers applying for continued enrollment, in the Medi-Cal program shall be certified for participation in the Medicare program of the Federal Social Security Act (Title XVIII), if they provide services that are included in the Medicare scope of benefits and if they provide those services to persons who are eligible beneficiaries of the Medicare program.

(e) Any provider who requests the performance of a clinical laboratory test or examination for a Medi-Cal beneficiary, or upon a biological specimen derived from a Medi-Cal beneficiary, shall provide with the request to the clinical laboratory diagnostic information relevant to the test or examination for which the request is made, including the latest International Classification of Diseases, 9th Revision, or the latest published editions or amendments thereto, Clinical Modification (ICD-9-CM) code numbers, to the highest level of specificity indicating medical necessity for all laboratory tests as required under the Medicare program pursuant to 42, U.S.C., Section 1395u(p) and 42, CFR, Section 424.32.

(f) In addition to meeting and complying with all applicable requirements specified in Articles 1, 2, and 3, any place where a provider, as defined in Section 51051(a), renders laboratory or clinical laboratory services as defined in Section 51137.2 and any person performing, supervising, consulting on, or directing such laboratory or clinical laboratory services shall meet and maintain compliance with the requirements of Section 51211.2.

(g) Medi-Cal provider applicants or providers shall meet and maintain compliance with the requirements of Section 51200.01.

Title 22, California Code of Regulations, Section 51200.01, Established Place of Business

(a) Every applicant or provider shall be required to demonstrate an established place of business appropriate and adequate for the services billed or claimed to the Medi-Cal program. "An established place of business" means a business address of the provider or applicant that meets all of the following criteria:

(1) is open and conducting business at the time the application is submitted for participation in the Medi-Cal program;
(2) has sufficient capital for start up, and sufficient income to sustain a financially sound business. This criterion shall be shown by financial records including, but not limited to, bank statements, loan documents, promissory notes, invoices, accounts receivable, business tax records, and contractual agreements;
(3) is located in a building either owned by the applicant or provider, or the applicant or provider has obtained a signed lease agreement;
(4) has adequate stock and staff to meet current and anticipated service requirements for its business;
(5) operates in compliance with Section 51000.30(d);
(6) has Worker's Compensation insurance as required by state law;
(7) obtains and maintains Comprehensive Liability insurance coverage in an amount not less than $100,000 per claim, with a minimum annual aggregate of not less than $300,000, from an authorized insurer pursuant to Section 700 of the Insurance Code;
(8) obtains and maintains, for any individual licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act, or the Chiropractic Initiative Act, Professional Liability insurance coverage in an amount not less than $100,000 per claim, with a minimum annual aggregate of not less than $300,000, from an authorized insurer pursuant to Section 700 of the Insurance Code;
(9) has the necessary equipment, office supplies and facilities available to carry out its business, including storage and retrieval of all documentation as required by Section 51476; and,
(10) has the necessary service agreements to process cash and credit card transactions;
(11) has regular and permanently posted business hours;
(12) is visibly identifiable as a medical/healthcare provider or business, with permanently attached signage that identifies the name of the provider or business.

(b) If the applicant or provider intends to provide or currently provides durable medical equipment as defined in Section 51160, or is a medical device retailer as defined in Section 51251, or is a pharmacy as defined in Section 51106 and provides pharmaceutical services as defined in Section 51107, all criteria in subsection (a) above must be met, and the applicant or provider must additionally meet the following criteria:

(1) provides service to the general public on a walk-in basis during regular business hours (unless the explanation provided on application is acceptable to the Department);
(2) has adequate inventory either in stock on the premises, or in a warehouse under the applicant's or provider's direct control, to meet current and anticipated sales volume;

(c) The applicant or provider must have an established place of business at the time of any inspection by the Department. Failure to show an established place of business warrants denial of an application or shall make a provider subject to temporary suspension from the Medi-Cal program, which shall include temporary deactivation of all provider numbers effective 15 days from the date of notice to the provider.

Title 17, California Code of Regulations, Section 2643.10, HIV Reporting by Laboratories

(a) The laboratory director or authorized designee shall create a Partial Non-Name Code (as specified in Section 2641.77) for each confirmed HIV test.
(b) The laboratory director or authorized designee shall, within seven calendar days of determining a confirmed HIV test, report the confirmed HIV test to the Health Officer of the local health jurisdiction where the health care provider facility is located. The report shall include the:
  (1) Partial Non-Name Code of the patient; and
  (2) Name, address, and telephone number of the health care provider and the facility that submitted the biological specimen to the laboratory, if different.; and
  (3) Name, address, and telephone number of the laboratory; and
  (4) Laboratory report number as assigned by the laboratory; and
  (5) Laboratory results of the test performed; and
  (6) Date the biological specimen was tested in the laboratory.
(c) A laboratory shall not transmit a patient's personal information to the local health department.
(d) A laboratory that receives incomplete patient data from a health care provider for a biological specimen with a confirmed HIV test, shall contact the submitting health care provider to obtain the information required pursuant to Section 2643.5(b)(1)-(5), prior to reporting the confirmed HIV test to the local Health Officer.
(e) A laboratory shall convey the patient's Partial Non-Name Code to the submitting health care provider when reporting confirmed HIV test results.
(f) If a laboratory transfers a biological specimen to another laboratory for testing, the laboratory that first receives the biological specimen from the health care provider shall report confirmed HIV tests to the local Health Officer.
(g) Laboratories shall not submit reports to the local health department for confirmed HIV tests for patients of an Alternative Testing Site or other anonymous HIV testing program, a blood bank, a plasma center, or for participants of a blinded and/or unlinked seroprevalence study.
(h) When a California laboratory receives a biological specimen for testing from an out-of-state laboratory or health care provider, the California director of the laboratory shall ensure that a confirmed HIV test is reported to the state health department in the state where the biological specimen originated.
(i) When a California laboratory receives a report from an out of state laboratory that indicates evidence of a confirmed HIV test for a California patient, the California laboratory shall notify the local Health Officer and health care provider in the same manner as if the findings had been made by the California laboratory.
(j) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the laboratory except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

Business and Professions Code, Section 1225

(a) In order to carry out this chapter, any duly authorized representative of the department may do any of the following:
   (1) Enter or inspect on an announced or unannounced basis any building, premise, equipment, materials, records, or information at any reasonable time to secure compliance with, or prevent a violation of this chapter or the regulations adopted pursuant thereto.
   (2) Inspect, photograph, or copy any records, reports, test results, test specimens, or other information related to the requirements of this chapter or the regulations adopted pursuant thereto.
   (3) Secure any sample, photograph, or other evidence from any building or premise for the purpose of enforcing this chapter or the regulations adopted pursuant thereto.

(b) The department may cooperate with, or assist persons licensed under this chapter, or other qualified persons, in evaluating laboratory procedures and techniques necessary to achieve and maintain high quality performance in clinical laboratories.

Business and Professions Code, Section 1211

(a) As used in this chapter, "owner" means any person with an ownership or control interest in a clinical laboratory.
(b) "Person with an ownership or control interest" means a person, partnership, or corporation that meets any of the following descriptions:
  (1) Has an ownership interest totaling 5 percent or more in a clinical laboratory.
  (2) Has an indirect ownership interest equal to 5 percent or more in a clinical laboratory.
  (3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a clinical laboratory.
  (4) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the clinical laboratory
  if that interest equals at least 5 percent of the value of the property or assets of the clinical laboratory.
  (5) Is an officer or director of a clinical laboratory that is organized as a corporation.
  (6) Is a partner in a clinical laboratory that is organized as a partnership with no more than 25 partners, general or limited.
  (7) Is a partner who exercises any operational or managerial control over a clinical laboratory organized as a partnership with more than 25 partners, general or limited.
(c) As used in this chapter "ownership interest" means the possession of equity in capital, stock, or profits.
(d) "Indirect ownership interest" means an ownership interest in an entity that has an ownership interest in a clinical laboratory, and includes an ownership interest in any entity that has an indirect ownership interest in a clinical laboratory.
(e) "Change in ownership" means any change in the persons who are owners.
(f) "Major change in ownership" means a change in ownership where 50 percent or more of the ownership interest is owned by persons other than the owners to whom the current clinical laboratory license or registration is issued.
(g) "Change in name" means any change in the name under which the laboratory operates or is doing business.
(h) "Change in location" means any change in the street and city address, or the site or place within the street and city address, for which a license or registration is issued.
(i) "Change in laboratory director" means any change in the laboratory director or directors to whom the current license or registration is issued.
(j) "Major change in laboratory directorship" means a change in laboratory director or directors resulting in the situation where less than 50 percent of the laboratory directors to whom the current laboratory license or registration is issued remain after the change.

Driving & Parking Instructions to the Department of Health Services
Office of Medi-Cal Procurement
9800 Old Winery Place
Sacramento, CA 95827

<u>From the West</u>: Take US 50 East. Exit Bradshaw Road and turn left. Turn right on Folsom Boulevard and continue east. Turn right on Horn Road and then turn right on Old Winery Place. Continue on Old Winery Place till the end of the cul-de-sac and enter the last driveway on the left. 9800 Old Winery Place is the building in the back.

<u>From the East</u>: Take US 50 West. Exit Bradshaw Road and turn right. Turn right on Folsom Boulevard and continue east. Turn right on Horn Road and then turn right on Old Winery Place. Continue on Old Winery Place till the end of the cul-de-sac and enter the last driveway on the left. 9800 Old Winery Place is the building in the back.

Free parking is available in the lot.