



SOLICITATION FOR OFFERS

for

**PHARMACEUTICAL MANUFACTURER(S) TO ENTER INTO CONTRACT
NEGOTIATIONS TO IMPLEMENT HEPATITIS C SUBSCRIPTION MODEL**

STD/HIV PROGRAM

OFFICE OF PUBLIC HEALTH

Offer Due Date/Time: February 28, 2019

Release Date: January 10, 2019

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SOLICITATION FOR OFFERS
FOR
PHARMACEUTICAL MANUFACTURER TO ENTER INTO CONTRACT NEGOTIATIONS
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1.1 Purpose

The purpose of this Solicitation for Offers (SFO) is to obtain competitive Offers from qualified pharmaceutical manufacturers who are interested in providing a commitment to enter into contract negotiations that obligate the successful Manufacturer(s) to deliver at least: (a) an unrestricted supply of direct-acting antiviral (DAA) medications each year for the term of the resulting contract (b) at an annual cost not to exceed the Total State Spend on hepatitis C medications in the Medicaid population, estimated to be \$30 million dollars, and the Total State Spend on hepatitis C medications in the Corrections population, estimated to be \$5 million dollars, for State Fiscal Year 2018; and (c) any additional complementary services that such manufacturer(s) deem necessary and appropriate to promote the strategies of the Hepatitis C Statewide Elimination Program, reproduced below.

1.1.1 LDH Principal Offices and Programs

LDH is comprised of the Medical Vendor Administration (Medicaid), the Office for Citizens with Developmental Disabilities (OCDD), the Office of Behavioral Health (OBH), the Office of Aging and Adult Services (OAAS), and the Office of Public Health (OPH). Under the general supervision of the Secretary, these principal offices perform the primary functions and duties assigned to LDH.

In addition to encompassing the program offices, LDH has an administrative office known as the Office of the Secretary (OS), a financial office known as the Office of Management and Finance (OMF), and various bureaus and boards. The Office of the Secretary is responsible for establishing policy and administering operations, programs, and affairs.

LDH's Office of Public Health oversees the STD/HIV Program (SHP) which: administers statewide and regional programs designed to prevent the transmission of sexually transmitted disease (STD) and human immunodeficiency virus (HIV), ensures the availability of quality medical and social services for those diagnosed with an STD or HIV, and tracks the impact of the STD and HIV epidemics in Louisiana.

1.1.2 Hepatitis C Epidemic in Louisiana

Hepatitis C is a deadly virus transmitted through blood and causing severe inflammation and scarring in the liver, often resulting in chronic liver disease, cirrhosis, liver cancer, and death. In Louisiana, at least 90,900 people are currently infected with hepatitis C, a disproportionate number of whom have low-income and/or are incarcerated. About 39,000 people in Louisiana's Medicaid Program and the Louisiana Department of Public Safety and Corrections are known to be chronically infected with hepatitis C.

Moreover, the rate of new infections is growing dramatically as a result of injection drug use associated with the opioid epidemic.

The introduction and continued development of direct-acting antivirals (DAAs) has revolutionized the treatment of hepatitis C. DAAs achieve cures—or sustained virologic responses, as they are called clinically—at rates as high as 99%. However, the high cost of treatment restricts the State from providing this medication to larger numbers of patients, including those in Medicaid. Last year, less than 3% of the infected Medicaid population received treatment despite the high State spend on DAAs.

- The State believes a transformational change in access to hepatitis C treatment is required to have any chance of slowing and, ultimately, reversing this growing epidemic. Louisiana Medicaid currently covers DAAs only for members with the most advanced disease or those co-infected with HIV. This limited coverage approach reflects the high cost of DAA treatment and limited State resources, requiring those with hepatitis C to experience more serious health conditions before qualifying for treatment. Leaving tens of thousands of Louisianans untreated not only presents a concern for the infected individuals themselves but it serves to further fuel the spread of the epidemic as well.
- As a result, the Department is pursuing an innovative approach to eliminating hepatitis C that will enable the State to expand treatment eligibility to all infected individuals in Medicaid and Corrections without further increasing state expenditures on DAAs beyond the Total State Spend in State Fiscal Year 2018. The goal of this approach is to address the current public health crisis before it becomes even more widespread.

1.2 Goals and Objectives

To solve the complex public health epidemic caused by high rates of hepatitis C infection in Louisiana, this Solicitation for Offers seeks to leverage public and private resources to reduce health inequities in hepatitis treatment, while increasing quality of care and unfettered access to lifesaving medications. More specifically, the State intends to partner with a pharmaceutical manufacturer holding a patent on a direct acting antiviral medication that provides a cure to a broad section of patients infected with chronic hepatitis C to provide unrestricted access to such medication for at risk populations without increasing the current State spend.

1.3 Term of Contract

The term of any contract resulting from this SFO shall begin on or about July 1, 2019 and is anticipated to end June 30, 2024.

No contract/amendment shall be valid, nor shall the LDH be bound by the contract/amendment, until it has first been executed by the head of the using department, or his designee. Total contract term, with extensions, shall not exceed five (5) years.

1.4 Definitions

Complementary Services	Complementary services are any services a Manufacturer offers to provide, at no additional cost to the State, as part of a competitive response to this SFO that are designed to advance the goals of the Hepatitis C Elimination Program.
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Contractor	Any person having a contract with a governmental body; the selected Manufacturer.
Corrections or Corrections population	The Louisiana Department of Public Safety and Corrections is the state system responsible for the care and custody of incarcerated people across Louisiana. The Corrections population refers to inmates in the custody of the Louisiana Department of Public Safety and Corrections.
Department or LDH or State	Louisiana Department of Health
Direct-Acting Antivirals or DAAs	Direct-acting Antivirals, or DAAs, are medications targeted at specific steps within the life cycle of the hepatitis C virus. DAAs are molecules that target specific nonstructural proteins of the virus and result in disruption of viral replication and infection.
Discussions	For the purposes of this SFO, a formal, structured means of conducting written or oral communications/presentations with responsible Manufacturers who submit offers in response to this SFO.
Dual Eligible Beneficiaries	Individuals who are both (i) entitled to Medicare Part A and/or Part B and (ii) eligible for some form of Medicaid benefit.
Hepatitis C	Hepatitis C is a liver disease caused by the hepatitis C virus: the virus can cause both acute and chronic hepatitis, ranging in severity from a mild illness lasting a few weeks to a serious, lifelong illness. A significant number of those who are chronically infected will develop cirrhosis or liver cancer.
May and Can	The terms “may” and “can” denote an advisory or permissible action.
Must	The term “must” denotes mandatory requirements.
Manufacturer or Offeror	A firm or individual who responds to this SFO
Medicaid or Medicaid population	Medicaid is a joint federal and state program that provides health coverage to low-income individuals and families. Although the federal government establishes the general rules for Medicaid, specific requirements are established by each state. The Louisiana Medicaid Program operates within the Louisiana Department of Health. The Medicaid population refers to all individuals enrolled or eligible to enroll in the Louisiana Medicaid Program.
Medicaid Best Price Policy	The Medicaid “best price” policy, as set forth in 42 CFR 447.505, requires that a manufacturer must offer state Medicaid programs the best price given to any other purchaser with a mandatory rebate of 23.1% off the Average Manufacturer Price or AMP as defined in federal statute 42 CFR 447.504.
Redacted Offer	The removal of confidential and/or proprietary information from one copy of the offer for public records purposes
SFO	Solicitation for Offers
Shall and Will	The terms “shall” and “will” denote requirements.
Should	The term “should” denotes a desirable action.
State	The State of Louisiana
State Fiscal Year 2018	The State of Louisiana’s 2018 fiscal year began on July 1, 2017 and ended on June 30, 2018.
Subscription Model	The Subscription Model is a maximum five-year contract pursuant to which the State will select a pharmaceutical manufacturer(s) holding a patent on a DAA that provides broad virologic coverage to a high percentage of patients with hepatitis C. Under this model, manufacturer(s) agree to: (1) supply unrestricted DAAs for treatment of individuals in Medicaid and Corrections regardless of fibrosis score or abstinence from substance use, and (2) limit the Total State Spend for such medications to an amount equal to or less than the combined spending by Louisiana Medicaid (state and federal total) and the Louisiana Department of Corrections (state funds only) on DAAs in State Fiscal Year 2018.

Supplemental Rebate Agreement or SRA	Supplemental Rebate Agreement or SRAs are established between one or more state Medicaid programs and a drug manufacturer to negotiate lower prices than those set forth in the Department of Health and Human Services Secretary's national rebate agreement.
Third Party Liability	Third party liability refers to the legal obligation of third parties to pay part or all the expenditures for medical assistance furnished under a Medicaid state plan.
Total State Spend or State Spend	The Total State Spend is the State's total pre-rebate annual DAA spend on Medicaid, including federal and State funds, and Corrections patients initiating hepatitis C treatment in State Fiscal Year 2018 (excluding dual eligibles and third-party liability).
340b Covered Entity	The definition of "covered entities" includes six categories of hospitals: disproportionate share hospitals (DSHs), children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals (CAHs). Hospitals in each of the categories must be (1) owned or operated by state or local government, (2) a public or private non-profit corporation which is formally granted governmental powers by state or local government, or (3) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare. In addition, except for CAHs, hospitals must meet payer-mix criteria related to the Medicare DSH program. There are also ten categories of non-hospital covered entities that are eligible based on receiving federal funding. They include federally qualified health centers (FQHCs); FQHC "look-alikes"; state-operated AIDS drug assistance programs; the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics and programs; tuberculosis clinics, black lung clinics, Title X family planning clinics, sexually transmitted disease clinics; hemophilia treatment centers; Urban Indian clinics; and Native Hawaiian health centers.
340 Drug Pricing Program	<p>The 340B Drug Pricing Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Manufacturers participating in Medicaid, agree to provide outpatient drugs to covered entities at significantly reduced prices.</p> <p>Eligible health care organizations/covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. See the full list of eligible organizations/covered entities.</p> <p>To participate in the 340B Program, eligible organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs.</p>
340b Patient Definition	<p>To be eligible to receive 340B-purchased drugs, patients must receive health care services other than drugs from the 340B covered entity. The only exception is patients of State-operated or -funded AIDS drug purchasing assistance programs.</p> <p>An individual is a patient of a 340B covered entity (except for State-operated or funded AIDS drug purchasing assistance programs) only if:</p> <ul style="list-style-type: none"> the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under

	<p>contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and</p> <ul style="list-style-type: none"> the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
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1.5 Schedule of Events

<u>Event</u>	<u>Date</u>
SFO advertised in newspapers	January 10, 2019
Deadline for receipt of written inquiries	January 28, 2019 at 4:00 p.m. Central Time
Deadline to answer written inquiries on or about	February 11, 2019
Deadline for receipt of offers	February 28, 2019 at 4:00 p.m. Central Time
Presentations & Discussions (if applicable)	March 15, 2019 Location TBA
Notice of Intent to award announcement, on or about	April 15, 2019
45 Day Negotiation Period Begins	April 16, 2019
Contract execution, on or about	June 1, 2019
Effective Date of Contract	July 1, 2019

NOTE: The Department of Health reserves the right to revise this schedule. Revisions, if any, before the Offer Submission Deadline will be formalized by the issuance of an addendum to the SFO.

1.6 Offer Submittal

Firms or individuals who are interested in providing services requested under this SFO must submit an offer containing the mandatory information specified in the section 1.8. The offer must be received in hard copy (printed) version by the SFO Coordinator on or before the date and time specified in the Schedule of Events, or as revised by LDH. It is the sole responsibility of each Manufacturer to assure that its offer is delivered at the specified location prior to the deadline. Offers which, for any reason, are not so delivered will not be considered.

Manufacturer shall submit one (1) original hard copy, (5) duplicate hard copies, and one (1) electronic copy (on USB flash drive) of the entire offer. Manufacturer shall also submit one (1) electronic copy (on USB flash drive) of its Redacted offer, if applicable. All electronic copies must be in a searchable format.

The original hard copy of the offer and the Certification Statement attached thereto shall contain original signatures of those company officials or agents duly authorized to sign offers or contracts on behalf of the

organization. The original hard copy will be retained for incorporation into any contract resulting from this SFO.

A certified copy of a board resolution granting such authority should be submitted if the Manufacturer is a corporation.

No facsimile or emailed offers will be accepted.

Offers must be submitted via U.S. mail, courier or hand delivered to:

If courier mail or hand delivered:

Capucinca Harris-Roberts
Program Monitor/RFI Coordinator
Louisiana Department of Health
Office of Public Health
STD/HIV Program
1450 Poydras Street
Suite 2136
New Orleans, LA 70112
(504) 568-7474
Capucinca.harris-roberts@la.gov

If delivered via US Mail:

1.7 Qualification for Manufacturer

Manufacturer must be a pharmaceutical manufacturing company in good legal standing who holds a patent on at least one DAA. In addition, Manufacturer must produce evidence of a supply chain and stock inventory system capable of producing, supplying and shipping unrestricted DAA's to the State during the 5-year term.

1.7.1 Desirable Qualifications:

It is desirable that Manufacturers should meet the following qualifications prior to the deadline for receipt of offers:

- Holds a patent for a DAA that provides broad virologic coverage across populations.
- Existing infrastructure, staffing, and relationships with providers, pharmacies and the community in Louisiana that can be leveraged to support the State's Hepatitis C Elimination Program goals and its strategies.
- Trusted relationships and brand recognition among providers who currently prescribe DAAs.
- Marketing and advertising departments or relationships that can be leveraged to create branded materials and advertisements in multiple mediums.
- Sophisticated inventory and supply chain systems that provide timely data on cost and number of medications that are subject to any agreement or contract reached subsequent to this SFO;

- State-of-the-art surveillance and data management systems that can be leveraged to identify not only prevalence of disease but areas and populations for whom targeted interventions may be necessary for testing and treatment.

1.8 Scope of Work

The State is seeking a pharmaceutical manufacturer to partner in delivering a dual approach to eliminating hepatitis C in Louisiana:

- a. The initial strategy of the Hepatitis Elimination Program is the creation of the Subscription Model.

While the Total State Spend under the Subscription Model is an aggregate of the State's Medicaid and Corrections pre-rebate spending on DAAs in State Fiscal Year 2018, two separate arrangements, one for Medicaid and one for Corrections, are required. The most effective mechanisms the State has identified for effectuating these arrangements are:

- i. **Medicaid:** The successful Manufacturer will provide rebates to the State via Supplemental Rebate Agreements, effectively limiting the Total State Spend for DAAs in the Medicaid population. SRAs are agreements established between one or more state Medicaid programs and a drug manufacturer to negotiate lower prices than those set forth in the Department of Health and Human Services Secretary's national rebate agreement. In this case, Louisiana Medicaid will enter an SRA that will yield a set annual revenue for the DAA manufacturer at or below the State Fiscal Year 2018 Medicaid spend for DAAs. For example, this could be achieved paying the currently negotiated DAA price (inclusive of federal rebates only) until the Medicaid-attributed portion of the total subscription payment has been paid, after which the cost of any remaining Medicaid-related DAA purchases would be effectively \$0.01, regardless of volume.
- ii. **Corrections:** The successful Manufacturer will utilize the 340b Drug Pricing Program to effectively limit the Total State Spend for DAAs in the Corrections population. The 340B program was established by the federal government to allow covered entities to stretch scarce federal dollars by exempting deeply discounted prices negotiated with pharmaceutical manufacturers from the Medicaid 'best price' calculation. The 'best price' requirement ensures low drug prices for state Medicaid programs, but also creates a negative incentive for manufacturers to grant any one entity a deep discount as it would then become the 'best price' for all Medicaid programs. Negotiations with a 340B program covered entity are exempt from this requirement, protecting the DAA manufacturer contracting with the State from affecting their 'best price' through participation in the subscription model. For example, this could be achieved by having LSU Lallie Kemp Regional Medical Center, a 340B covered entity providing clinical services to inmates on behalf of the Department of Corrections, purchase DAAs for the Corrections population at a Medicaid Best Price Policy-exempt negotiated price. Much like the SRAs in Medicaid, the price for the Corrections DAA purchases would be adjusted over time to ensure it does not exceed the 2018 Total State Spend for the Corrections population.

- b. The second component is executing the following strategies that support the State’s broader Hepatitis C Elimination Program:
- i. Expand Provider Capacity to Treat hepatitis C – Most hepatitis C treatment in the State is currently overseen by infectious disease or liver specialists. In order to reach as many infected individuals as possible, primary care providers across the state will be taught how to diagnose and treat hepatitis C. They will also be trained to manage or make effective referrals to address conditions associated with hepatitis C infection, including advanced liver disease, cancer, and substance use disorder;
 - ii. Educate Public on Availability of Cure and Mobilize Priority Populations for Screenings – The Centers for Disease Control and Prevention (CDC) estimates that fewer than half of all individuals infected with hepatitis C know their status. In order to mobilize priority populations to undergo hepatitis C screening and treatment, public messaging must be developed. Key components of this public education campaign should include information regarding the risk factors for contracting hepatitis C, access to screening, the importance of treating hepatitis C even before symptoms appear, and the State’s unprecedented access to DAAs under the Subscription Model.
 - iii. Expand HCV Screening and Expedited Linkage to HCV Cure – Screening for hepatitis C is recommended for all individuals born between 1945 and 1965 and those who are at increased risk of infection such as people who inject drugs. Health care providers across the State will be mobilized to screen these priority populations and others, and ensure that all individuals with hepatitis C are linked to a care provider for treatment;
 - iv. Strengthen HCV Surveillance to Link Persons Previously Diagnosed to Treatment – LDH’s existing hepatitis C surveillance system will need to be upgraded to support the identification of individuals with chronic hepatitis C infections so they can be linked to care providers. Additional capabilities such as linking the system to provider-facing panel management and clinical decision support tools would enhance surveillance data with clinical information and support treatment monitoring across providers;
 - v. Implement Harm Reduction and Complementary Treatment Strategies – In addition to prioritizing curative treatment of individuals with hepatitis C, strategies to prevent new hepatitis C infections or reinfections must be employed. These strategies include expanding access to syringe service programs and increasing access to behavioral and medication assisted treatment for opioid use disorder;
 - vi. Extend Elimination Efforts to All Populations Within the State – A significant proportion of Louisianans infected with hepatitis C are neither Medicaid beneficiaries nor incarcerated. In order to truly achieve statewide elimination, the State will work with new and existing partners to expand treatment to these individuals, including commercial insurers, health systems, and entities serving the uninsured through other appropriate mechanisms.

All offers **must** include both of the following:

- A detailed, comprehensive pricing structure utilizing a Supplemental Rebate Agreement for participation that covers unrestricted DAA supply for the Medicaid population for the duration of the contract term at a cost not to exceed the State's current spend for DAAs in this population.
- A detailed, comprehensive pricing structure utilizing price negotiations with a 340b Covered Entity that covers unrestricted DAA supply for the Corrections population for the duration of the contract term at a cost not to exceed the State's current spend for DAAs in this population.

In addition, offers **may** include:

- A detailed, comprehensive pricing structure utilizing some other agreement or price negotiation vehicle for one or both populations so long as it complies with all elements of the Subscription Model and provides unlimited DAAs for both populations.

Irrespective of pricing structure, all offers **must** include the following:

- A detailed and specific delineation of what, if any, complementary services they intend to supply for each of the additional hepatitis C Elimination strategies outlined above. For each proposed complementary service, manufacturers should include sufficient information for the State to evaluate the value proposition each service provides. Categories of complementary services are not proscribed but rather provide an opportunity for Manufacturers to indicate a deep and comprehensive knowledge of the hepatitis C elimination goals and to offer solutions that match the Manufacturer's knowledge and strengths.

The following categories of services are illustrative but not exclusive: screening, patient and peer navigation, linkage and care coordination, promotional and educational materials, provider outreach and training, community outreach and education, direct medication observation, physician extender support and training, surveillance system enhancements including data streams and/or other software solutions that improve the quality and timeliness of identifying people infected with or at risk of contracting hepatitis C and discounted pricing for qualified uninsured citizens. If any complementary services apply only to one of the required populations, Medicaid or Corrections, please explicitly indicate which population will be served.

Responses shall include detailed information regarding the manufacturer's infrastructure and capacity around:

- a. Manufacturing, distributing, supplying, shipping and otherwise making available an adequate supply of DAAs to treat at least 10,000 Medicaid and/or incarcerated individuals per year.
- b. Manufacturer's proposed approach to distribution that ensures DAAs reach all eligible patients as defined by the Subscription Model as quickly as practicable.
- c. Supporting communication between the successful Manufacturer and the State which will be a key component of this Subscription Model. In particular, Manufacturers should identify their internal inventory management system and propose ways to exchange timely data

relative to the number and per treatment cost of DAAs being supplied under the resulting contract.

- d. Surveilling and analyzing population health level data, treatment monitoring, and analytic capacities, which will leverage and support the State's Hepatitis C Elimination Program goals.

1.8.1 Task and Services

The Proposer selected for the Project will serve as a partner for the State in its efforts to eliminate hepatitis C as a public health threat. By working collaboratively and innovatively to provide unrestricted access to DAAs, the Proposer and State will remove the traditional barriers to hepatitis C treatment such as fibrosis score and sobriety restrictions, and support Medicaid and Corrections patients in accessing lifesaving drugs while promoting complementary strategies to help screen, support and treat such populations.

1.8.2 Deliverables

General Requirements:

Assessment of and upgrade to any internal manufacturing or supply chain infrastructure to ensure strict compliance with the terms of the Subscription Model and to make available all resources required to provide the complementary services in support of the strategies of the hepatitis C Elimination Program.

Programmatic Requirements:

On or about May 1st, enter into SRA negotiations (if SRAs are part of the successful offer), 340b price negotiations (if 340b is part of the successful offer), and/or negotiations around another mutually agreed upon alternative mechanism, (if such mechanism is part of the successful offer), in good faith and with the intention of executing a mutually beneficial agreement that conforms to the terms of this SFO and the successful offer. Thereafter, on or about June 1, 2019, enter scale up and a plan for a firm go-live date on July 1, 2019.

Operations Requirements:

Manufacturing and supply chain infrastructure necessary to meet the terms of the Subscription Model.

Staffing Requirements/Qualifications:

Maintain sufficient key staff to support the obligations undertaken in this SFO and any resulting agreements.

Record keeping requirements:

Comply with all federal and state records requirements; maintain sufficient records and timely data systems to assist the State in tracking the amount of the spend in each population.

Reporting Requirements:

Comply with all federal and state reporting requirements, including but not limited to the Medicaid and 340b Drug Pricing Programs.

1.8.3 Technical Requirements

The Contractor will be required to transmit all non-proprietary data, which is relevant for analytical purposes to LDH on a regular schedule in XML format. Final determination of relevant data will be made by LDH based on collaboration between both parties. The schedule for transmission of the data will be established by LDH and dependent on the needs of the Department related to the data being transmitted. XML files for this purpose will be transmitted via SFTP to the Department. Any other data or method of transmission used for this purpose must be approved via written agreement by both parties.

- The contractor is responsible for procuring and maintaining hardware and software resources which are sufficient to successfully perform the services detailed in this SFO.
- The contractor must adhere to state and federal regulations and guidelines as well as industry standards and best practices for systems or functions required to support the requirements of this SFO.
- Unless explicitly stated to the contrary, the contractor is responsible for all expenses required to obtain access to LDH systems or resources, which are relevant to successful completion of the requirements of this SFO. The contractor is also responsible for expenses required for LDH to obtain access to the Contractor's systems or resources, which are relevant to the successful completion of the requirements of this SFO. Such expenses are inclusive of hardware, software, network infrastructure and any licensing costs.
- Any confidential information must be encrypted to FIPS 140-2 standards when at rest or in transit.
- Contractor owned resources must be compliant with industry standard physical and procedural safeguards (NIST SP 800-114, NIST SP 800-66, NIST 800-53A, ISO 17788, etc.) for confidential information (HITECH, HIPAA Part 164).
- Any contractor use of flash drives or external hard drives for storage of LDH data must first receive written approval from the Department and upon such approval shall adhere to FIPS 140-2 hardware level encryption standards.
- All contractor utilized computers and devices must:
 - Be protected by industry standard virus protection software, which is automatically updated on a regular schedule.
 - Have installed all security patches, which are relevant to the applicable operating system, and any other system software.
 - Have encryption protection enabled at the Operating System level

1.8.4 Project Requirements

Not applicable to this SFO.

1.9 Evaluation

Offers that pass the preliminary screening and mandatory requirements review will be evaluated based on information provided in the offer. The evaluation will be conducted according to the following:

1.9.1 Evaluation Criteria and Assigned Weights

The evaluation will be conducted according to the following:

Evaluation Components	Possible Points
Relevant Corporate Experience:	45
Approach & Methodology: SRAs in Medicaid Population:	150
Approach & Methodology: 340b in Corrections Population:	150
Approach & Methodology: Additional Mechanisms:	45
Pricing Structure:	250
Complementary Strategies:	150
Existing In-state infrastructure:	45
Data analytics & surveillance capabilities:	45
Veteran/Hudson Initiative (12%)	120
Total Possible Points	1,000

Manufacturer must receive a minimum score of 350 points (50%) of the total available points in the categories of Approach and Methodology: SRAs in Medicaid Population, Approach & Methodology: 340b in Corrections Population, Pricing Structure & Complementary Strategies to be considered responsive to the SFO. **Offers not meeting the minimum score shall be rejected.**

1.10 Offer Response Format

Offers submitted for consideration should follow the format and order of presentation described below:

An item-by-item response to the Solicitation for Offers is requested.

There is no intent to limit the content of the offers, and Manufacturers may include any additional information deemed pertinent. Emphasis should be on simple, straightforward and concise statements of the Manufacturer's ability to satisfy the requirements of the SFO.

1.10.1 Cover Letter

A cover letter should be submitted on the Manufacturer's official business letterhead explaining the intent of the Manufacturer.

1.10.2 Table of Contents

The offer should be organized in the order contained below.

Requested Offer Outline:

- Relevant Corporate Experience
- Approach and Methodology

- Personnel Qualifications
- Veteran and Hudson Initiative Programs Participation
- Additional Information
- Pricing Analysis
- Complementary Services

1.10.3 Executive Summary

This section serves to introduce the scope of the offer. It shall include administrative information including: Manufacturer contact name and phone number, and the stipulation that the offer is valid for a time of at least 90 calendar days from the date of submission. This section should also include a summary of the Manufacturer's qualifications and ability to meet the State department's overall requirements in the timeframes set by the department.

The executive summary should include a positive statement of compliance with the terms of the SFO. If the Manufacturer cannot comply with any of those terms, an explanation of each exception should be supplied. The Manufacturer should address the specific language in the SFO and submit whatever exceptions or exact contract modifications that its firm may seek. While final wording will be resolved during contract negotiations, the intent of the provisions will not be substantially altered.

Offers should include information that will assist the Department in determining the level of quality and timeliness that may be expected. The Department shall determine, at its sole discretion, whether the SFO provisions have been reasonably met. The offer shall describe the background and capabilities of the Manufacturer, give details on how the services will be provided, and shall include a breakdown of proposed costs. Work samples may be included as part of the offer.

Offers should address how the Manufacturer intends to assume complete responsibility for timely performance of all contractual responsibilities in accordance with federal and state laws, regulations, policies, and procedures.

1.10.4 Relevant Corporate Experience

The Manufacturers shall give a brief description of their company including brief history, corporate or organization structure, number of years in business, and copies of its latest financial statement, preferably audited.

The offer should indicate that the Manufacturer's firm has a record of prior successful experience in the implementation of services of the same or similar complexity and scale. Manufacturers should include statements specifying the extent of responsibility on prior projects and a description of the projects scope and similarity to the projects outlined in this SFO. All experience under this section should be in sufficient detail to allow an adequate evaluation by the Department. The Manufacturer should have, within the last 24 months, implemented a project of similar scope and size. Manufacturers should give at least two customer references for projects implemented in at least the last 24 months. References shall include the name, email address and telephone number of each contact person.

In this section, a statement of the Manufacturer's involvement in litigation that could affect this work shall be included. If no such litigation exists, Manufacturer shall so state.

Manufacturers should clearly describe their ability to exceed the qualifications described in the Mandatory Qualifications for Manufacturer section.

Manufacturers should clearly describe their ability to exceed the desired qualifications described in the Desirable Qualifications for Manufacturer section.

1.10.5 Approach and Methodology

Offers should define the Manufacturer's functional approach in providing services and identify the tasks necessary to meet the SFO requirements of the provision of services, as outlined in Part 2. Offers should include enough information to satisfy evaluators that the Manufacturer has the appropriate experience, knowledge and qualifications to perform the scope of services as described herein. While the State has identified certain parameters within which the Subscription Model must operate, this SFO is also an invitation for Manufacturers to provide a detailed framework for identifying ways they can leverage their strengths to work collaboratively and creatively with the State to eliminate hepatitis C as a public health problem.

Manufacturers should respond to all requested areas. As a general matter, the Approach and Methodology section should include at a minimum the DAA the Manufacturer is offering, the percentage of the population with hepatitis C that would be covered by such DAA and the mechanisms for supplying and distributing unrestricted DAAs to the Medicaid and Corrections populations. More specifically, this section should include:

Administrative Data

- This section should contain summary information about the Manufacturer's organization. This section should state Manufacturer's knowledge and understanding of the needs and objectives of LDH as related to the scope of this SFO. Manufacturer should further cite its ability to satisfy the requirements of this SFO.
- This section should include a description of how the Manufacturer's organizational components communicate and work together in both an administrative and functional capacity from the top down. This section should contain a brief summary setting out the Manufacturer's management philosophy including, but not limited to, the role of Quality Control, Professional Practices, Supervision, Distribution of Work and Communication Systems. This section should include an organizational chart displaying the Manufacturer's overall structure.
- This section should also include the following information:
 - Location of Administrative Office with Full Time Personnel, include all office locations (address) with full time personnel;
 - Name and address of principal officer;
 - Name and address for purpose of issuing checks and/or drafts;
 - For corporations, a statement listing name(s) and address(es) of principal owners who hold five percent interest or more in the corporation;

- If out-of-state Manufacturer, give name and address of local representative; if none, so state;
- If any of the Manufacturer's personnel named is a current or former Louisiana state employee, indicate the Department where employed, position, title, termination date, and social security number;
- If the Manufacturer was engaged by LDH within the past twenty-four (24) months, indicate the contract number and/or any other information available to identify the engagement; if not, so state;
- Manufacturer's state and federal tax identification numbers; and
- Veteran/Hudson Initiative: Manufacturer should demonstrate participation in Veteran Initiative and Hudson Initiative Small Entrepreneurships or explanation if not applicable. (See Attachment I)

Work Plan/Project Execution

- The Manufacturer should articulate an understanding of, and ability to effectively implement services as outlined within Section III (Scope of Work) of the SFO. In this section, the Manufacturer should state the approach it intends to use in achieving each objective of the project as outlined, including a project work plan and schedule for implementation. In particular, the Manufacturer should:
 - Provide a written explanation of the organizational structures of both operations and program administration, and how those structures will support service implementation. Individual components should include plans for supervision, training, technical assistance, as well as collaboration as appropriate.
 - Provide a strategic overview including all elements to be provided.
 - Provide an operational overview for the Manufacturer's proposed distribution approach for DAAs, plan and mechanism for generating and delivering timely Subscription Model data to the State, and a detailed offer for all complementary services.
 - Demonstrate knowledge of services to be provided and effective strategies to achieve objectives and effective service delivery.
 - Describe approach and strategy for project oversight and management.
 - Demonstrate an understanding of and ability to implement data collection as needed.
 - Articulate the ability to develop and implement an All Hazards Response plan in the event of an emergency event.
 - Identify all assumptions or constraints on tasks.
 - Document procedures to protect the confidentiality of records in LDH databases, including records in databases that may be transmitted electronically via e-mail or the Internet.
- Manufacturer must clearly outline the solution's technical approach as it relates to a service-oriented architecture. Details should include a description of capability and potential strategy for integration with future LDH wide enterprise components as they are established, specifically making use of an enterprise service business for managing touch points with other systems, integration with a master data management solution and flexibility to utilize a single identity and

access management solution. The contractor shall clearly identify any systems or portions of systems outlined in the offer, which are considered proprietary in nature.

- If the Manufacturer intends to subcontract for portions of the work, the Manufacturer should identify any subcontractor relationships and include specific designations of the tasks to be performed by the subcontractor. Information required of the Manufacturer under the terms of this SFO shall also be required for each subcontractor. The prime contractor shall be the single point of contact for all subcontract work.

1.10.6 Personnel Qualifications

Manufacturers should state job responsibilities, workload and lines of supervision. An organizational chart identifying key individuals and their job titles and major job duties should be included. The organizational chart should show lines of responsibility and authority.

Key personnel and the percentage of time directly assigned to the project should be identified.

Résumés of such key personnel should be included. Résumés of proposed personnel should include, but not be limited to:

- Experience with Manufacturer,
- Previous experience in projects of similar scope and size.
- Educational background, certifications, licenses, special skills, etc.

If subcontractor personnel will be used, the Manufacturer should clearly identify these persons, if known, and provide the same information requested for the Manufacturer's personnel.

Manufacturers should clearly describe their ability to exceed the desired qualifications described in the Desirable Qualifications for Manufacturer section.

1.10.7 Veteran and Hudson Initiative Programs Participation

Veteran-Owned and Service-Connected Disabled Veteran-Owned Small Entrepreneurships (Veteran Initiative) and Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) participation

- a. Twelve percent (12%) of the total evaluation points in this SFO are reserved for Manufacturers who are certified small entrepreneurships, or who will engage the participation of one or more certified small entrepreneurships as subcontractors. Reserved points shall be added to the applicable Manufacturers' evaluation score as follows:
- b. Manufacturer Status and Allotment of Reserved Points:
 - i. If the Manufacturer is a certified Veterans Initiative small entrepreneurship, the Manufacturer shall receive points equal to twelve percent (12%) of the total evaluation points in this SFO.
 - ii. If the Manufacturer is a certified Hudson Initiative small entrepreneurship, the Manufacturer shall receive points equal to ten percent (10%) of the total evaluation points in this SFO.

- iii. If the Manufacturer demonstrates its intent to use certified small entrepreneurship(s) in the performance of contract work resulting from this solicitation, the Manufacturer shall receive points equal to the net percentage of contract work, which is projected to be performed by, or through certified small entrepreneurship subcontractors, multiplied by the appropriate number of evaluation points.
 - iv. The total number of points awarded pursuant to this Section shall not exceed twelve percent (12%) of the total number of evaluation points in this SFO.
- c. If the Manufacturer is a certified Veterans Initiative or Hudson Initiative small entrepreneurship, the Manufacturer must note this in its offer in order to receive the full amount of applicable reserved points.
- d. If the Manufacturer is not a certified small entrepreneurship, but has engaged one (1) or more Veterans Initiative or Hudson Initiative certified small entrepreneurship(s) to participate as subcontractors, the Manufacturer shall provide the following information for each certified small entrepreneurship subcontractor in order to obtain any applicable Veterans Initiative or Hudson Initiative points:
 - i. Subcontractor's name;
 - ii. Subcontractor's Veterans Initiative and/or the Hudson Initiative certification;
 - iii. A detailed description of the work to be performed; and
 - iv. The anticipated dollar value of the subcontract for the contract term.

Note – *it is not mandatory to have a Veterans Initiative or Hudson Initiative certified small entrepreneurship subcontractor. However, it is mandatory to include this information in order to receive any allotted points when applicable.*

- e. If multiple Veterans Initiative or Hudson Initiative subcontractors will be used, the above-required information should be listed for each subcontractor. The Manufacturer should provide a sufficiently detailed description of each subcontractor's work so the Department is able to determine if there is duplication or overlap, or if the subcontractor's services constitute a distinct scope of work from each other subcontractor(s).

1.10.8 Additional Information

As an appendix to its offer, if available, Manufacturers should provide copies of any policies and procedures manuals applicable to this contract, inclusive of organizational standards or ethical standards. This appendix should also include a copy of Manufacturer's All Hazards Response Plan, if available.

1.10.9 Certification Statement

The Manufacturer must sign and submit an original Certification Statement (See Attachment II)

1.10.10 Legibility/Clarity

Responses to the requirements of this SFO in the formats requested are desirable with all questions answered in as much detail as practicable. The Manufacturer's response should demonstrate an

understanding of the requirements. Offers prepared simply and economically, providing a straightforward, concise description of the Manufacturer's ability to meet the requirements of the SFO are also desired. Each Manufacturer shall be solely responsible for the accuracy and completeness of its offer.

1.10.11 Confidential Information, Trade Secrets, and Proprietary Information

All financial, statistical, personal, technical and other data and information relating to the State's operation which are designated confidential by the State and made available to the contractor in order to carry out the resulting contract, or which become available to the contractor in carrying out the resulting contract, shall be protected by the contractor from unauthorized use and disclosure through the observance of the same or more effective procedural requirements as are applicable to the State. The identification of all such confidential data and information as well as the State's procedural requirements for protection of such data and information from unauthorized use and disclosure shall be provided by the State in writing to the contractor. If the methods and procedures employed by the contractor for the protection of the contractor's data and information are deemed by the State to be adequate for the protection of the State's confidential information, such methods and procedures may be used, with the written consent of the State, to carry out the intent of this paragraph. The contractor shall not be required under the provisions of the paragraph to keep confidential any data or information, which is or becomes publicly available, is already rightfully in the contractor's possession, is independently developed by the contractor outside the scope of the contract or is rightfully obtained from third parties.

Under no circumstance shall the contractor discuss and/or release information to the media concerning this project without prior express written approval of the LDH.

Only information, which is in the nature of legitimate trade secrets or non-published financial data, shall be deemed proprietary or confidential. Any material within an offer identified as such must be clearly marked in the offer and will be handled in accordance with the Louisiana Public Records Act, R.S. 44: 1-44 and applicable rules and regulations. Any offer marked as confidential or proprietary in its entirety shall be rejected without further consideration or recourse.

In addition, if the State receives a public records request for information pursuant to the Louisiana Public Records Act, R.S. 44: 1-44 and an Offeror wishes to assert that information is confidential, the Offeror may seek a protective order from a court of proper jurisdiction preventing the release of such information. In such case, the Offeror agrees to hold the State harmless for any and all costs or fees incurred, including attorneys' fees, related to the State's refusal to release documents or other information over which confidentiality has been claimed.

1.10.12 Manufacturer Inquiries

Written questions regarding SFO requirements or Scope of Services must be submitted to the SFO Coordinator listed below. All communications relating to this SFO must be directed to the SFO Coordinator. All communications between Manufacturers and other LDH staff members concerning this SFO shall be strictly prohibited. Failure to comply with these requirements shall result in offer disqualification.

Capucinca Harris-Roberts
Program Monitor/RFI Coordinator
Louisiana Department of Health
Office of Public Health
STD/HIV Program
1450 Poydras Street
Suite 2136
New Orleans, LA 70112
(504) 568-7474
Capucinca.harris-roberts@la.gov

LDH will consider written inquiries regarding the requirements of the SFO or Scope of Services before the date specified in the Schedule of Events. To be considered, written inquiries and requests for clarification of the content of this SFO must be received at the above address or via email address by the date specified in the Schedule of Events. Any and all questions directed to the SFO Coordinator will be deemed to require an official response and a copy of all questions and answers will be posted by the date specified in the Schedule of Events to the following web link:

<http://new.ldh.louisiana.gov/index.cfm/newsroom/category/47>

Action taken as a result of verbal discussion shall not be binding on the Department. Only written communication and clarification from the SFO Coordinator shall be considered binding.

Only Capucinca Harris-Roberts has the authority to officially respond to a Manufacturer's questions in writing on behalf of LDH. Any communications from any other individuals shall not be binding to LDH.

Relevant material related to this SFO will be posted at the following web address:
<http://new.dhh.louisiana.gov/index.cfm/newsroom/category/47>

Blackout Period

The blackout period is a specified period during a competitive sealed process in which any Manufacturer, Offeror, or its agent or representative, is prohibited from communicating with any state employee or contractor of the State involved in any step in the process about the process. The blackout period applies not only to state employees, but also to any contractor of the State and any private entity that is involved in the solicitation. "Involvement" in the process includes but may not be limited to project management, design, development, implementation, management, development of specifications, and evaluation of offers. All solicitations will identify a designated contact person, as per Manufacturer Inquiries section of this SFO. All communications to and from potential Offerors, vendors and/or their representatives during the blackout period must be in accordance with this solicitation's defined method of communication with the designated contact person. The blackout period will begin upon posting of the solicitation. The blackout period will end when the contract is awarded.

In those instances in which a prospective Manufacturer is also an incumbent contractor, the State and the incumbent contractor may contact each other with respect to the existing contract only. Under no circumstances may the State and the incumbent contractor and/or its representative(s) discuss the blacked-out process.

Any Offeror or state contractor who violates the blackout period may be liable to the State in damages and/or subject to any other remedy allowed by law.

Any costs associated with cancellation or termination will be the responsibility of the Offeror.

Notwithstanding the foregoing, the blackout period shall not apply to:

- Duly noticed site visits and/or conferences for Offerors;
- Oral presentations during the evaluation process; and
- Communications regarding this solicitation between any person and LDH staff provided the communication is limited strictly to matters of procedure. Procedural matters include deadlines for decisions or submission of offers and the proper means of communicating regarding the process but shall not include any substantive matter related to the requirements of the SFO.

1.11 Errors and Omissions in Offer

The Department reserves the right to seek clarification of any offer for the purpose of identifying and eliminating minor irregularities or informalities.

Changes, Addenda, Withdrawals

The Department reserves the right to change the schedule of events or revise any part of the SFO by issuing an addendum to the SFO at any time. Addenda, if any, will be posted at:

<http://new.ldh.louisiana.gov/index.cfm/newsroom/category/47>

It shall be the responsibility of the Manufacturer to check the website for addenda to the SFO.

1.12 Withdrawal of Offer

A Manufacturer may withdraw an offer that has been submitted at any time up to the date and time the offer is due. To withdraw an offer, a written request signed by the authorized representative of the Manufacturer must be submitted to the SFO coordinator identified in the SFO, or his/her successor.

1.13 Waiver of Administrative Informalities

The Department shall reserve the right, at its sole discretion, to waive minor administrative informalities contained in any offer.

1.14 Offer Rejection/SFO Cancellation

Issuance of this SFO in no way shall constitute a commitment by LDH to award a contract(s) or to enter into a contract after an award has been made. The Department reserves the right to take any of the following actions that it determines to be in its best interest:

1. Reject, in whole or part, all offers submitted in response to this solicitation;
2. Cancel this SFO; or
3. Cancel or decline to enter into a contract with the successful Manufacturer at any time after the award is made and before a contract is entered.

Ownership of Offer

All offers become the property of the Department and will not be returned to the Manufacturer. Except for those portions of any offer that have been properly designated by the Manufacturer as being proprietary or confidential, the Department retains the right to use any and all ideas or adaptations of ideas contained in any offer received in response to this solicitation. Selection or rejection of the offer will not affect this right. Once a contract is awarded, all offers will become subject to the Louisiana Public Records Act.

1.15 Cost of Offer Preparation

The Department shall not be liable for any costs incurred by Manufacturers prior to issuance of or entering into a contract. Costs associated with developing the offer, preparing for oral presentations, and any other expenses incurred by the Manufacturer in responding to this SFO shall be entirely the responsibility of the Manufacturer and shall not be reimbursed in any manner by the Department. The Manufacturer shall not include these costs or any portion thereof in the proposed contract cost. The Manufacturer is fully responsible for all preparation costs associated therewith even if an award is made but subsequently terminated by the Department.

The Manufacturer to which the contract is awarded assumes sole responsibility for any and all costs and incidental expenses that it may incur in connection with: (1) the preparation, drafting or negotiation of the final contract; or (2) any activities that the Manufacturer may undertake in preparation for, or in anticipation or expectation of, the performance of its work under the contract before the contract receives final approval from the State.

1.16 Taxes

The Louisiana Department of Revenue must determine that the prospective contractor is current in the filing of all applicable tax returns and reports and in payment of all taxes, interest, penalties, and fees owed to the State and collected by the Department of Revenue prior to the approval of this contract by LDH. The prospective contractor shall attest to its current and/or prospective compliance by signing the

Certification Statement, Attachment II, submitted with its offer, and agrees to provide its seven-digit LDR Account Number to the contracting department so that the prospective contractor's tax payment compliance status may be verified. The prospective contractor further acknowledges understanding that issuance of a tax clearance certificate by the Louisiana Department of Revenue is a necessary precondition to the approval and effectiveness of this contract. The contracting department reserves the right to withdraw its consent to this contract without penalty and proceed with alternate arrangements should the vendor fail to resolve any identified apparent outstanding tax compliance discrepancies with the Louisiana Department of Revenue within seven (7) days of such notification.

1.17 Determination of Responsibility

Determination of the Manufacturer's responsibility relating to this SFO shall be made according to the following standards listed below. The State must find that the selected Manufacturer:

- Has adequate financial resources for performance, or could obtain such resources as required during performance;
- Has the necessary experience, organization, technical qualifications, skills, and facilities, or can obtain them;
- Can comply with the proposed or required time of delivery or performance schedule;
- Has a satisfactory record of integrity, judgment, and performance; and
- Is otherwise qualified and eligible to receive an award under applicable laws and regulations.

Manufacturers should ensure that their offers contain sufficient information for the State to make its determination by presenting acceptable evidence of the above to perform the contracted services.

- The Manufacturer should include with its offer copies of audited financial statements for each of the last 3 years, including at least a balance sheet and profit and loss statement, or other appropriate documentation, which would demonstrate to LDH the Manufacturer's financial resources sufficient to conduct the project, as required by Section G.1.a above.

1.18 Use of Subcontractors

LDH shall have a single prime contractor as the result of any contract negotiation, and that prime contractor shall be responsible for all deliverables specified in the SFO and offer. This general requirement notwithstanding, Manufacturers may enter into subcontractor arrangements, however, the prime contractor shall acknowledge total responsibility for the entire contract.

If the Manufacturer intends to subcontract for portions of the work, the Manufacturer shall identify any subcontractor relationships and include specific designations of the tasks to be performed by the subcontractor. Information required of the Manufacturer under the terms of this SFO shall also be required for each subcontractor. The prime contractor shall be the single point of contact for all subcontract work.

Unless provided for in the contract with the State, the prime contractor shall not contract with any other party for any of the services herein contracted without the express prior written approval of the State.

For subcontractor(s), before commencing work, the contractor will provide letters of agreement, contracts or other forms of commitment, which demonstrate that all subcontractors through the following will satisfy all requirements pertaining to the contractor:

- The subcontractor(s) will provide a written commitment to accept all contract provisions.
- The subcontractor(s) will provide a written commitment to adhere to an established system of accounting and financial controls adequate to permit the effective administration of the contract.

1.19 Written or Oral Discussions/Presentations

The Department requires all Manufacturers reasonably susceptible of being selected for an award to provide an on-site presentation and/or demonstration. On-site presentations/demonstrations will allow the selected Manufacturers to demonstrate their unique capability to provide the services requested in the SFO.

Manufacturers selected for on-site presentations/demonstrations should:

- Provide a strategic overview of services to be provided,
- Summarize major strengths,
- Demonstrate flexibility and adaptability to handle both anticipated and unanticipated changes,
- If possible, have the project manager and key personnel in attendance to provide their view of the partnership envisioned with the Department.

The Department may adjust the Manufacturers' original scores based upon information received in the on-site presentations/demonstrations, using the original evaluation criteria.

1.20 Acceptance of Offer Content

All offers will be reviewed to determine compliance with administrative and mandatory requirements as specified in the SFO. Offers that are not in compliance will be rejected from further consideration.

1.21 Evaluation and Selection

The evaluation of offers will be accomplished by an evaluation team, to be designated by the State, which will determine the offer most advantageous to the State, taking into consideration price and the other evaluation factors set forth in the SFO.

The evaluation team may consult subject matter expert(s) to serve in an advisory capacity regarding any Manufacturer or offer. Such input may include, but not be limited to, analysis of Manufacturer financial statements, review of technical requirements, or preparation of cost score data.

1.22 Best and Final Offers (BAFO)

The State reserves the right to conduct a BAFO with one or more Manufacturers determined by the committee to be reasonably susceptible of being selected for award. If conducted, the Manufacturers selected will receive written notification of their selection, with a list of specific items to be addressed in

the BAFO along with instructions for submittal. The BAFO negotiation may be used to assist the State in clarifying the scope of work or to obtain the most cost-effective pricing available from the Manufacturers.

The written invitation to participate in BAFO will not obligate LDH to a commitment to enter into a contract.

1.23 Contract Award and Execution

The State reserves the right to enter into a contract based on the initial offers received without further discussion of the offers submitted. The State reserves the right to contract for all or a partial list of services offered in the offers.

The SFO, including any addenda added and the offer of the selected Manufacturer shall become part of any contract initiated by the Department.

In no event shall a Manufacturer submit its own standard contract terms and conditions as a response to this SFO. The Manufacturer should submit with its offer any exceptions or exact contract deviations that its firm wishes to negotiate. Negotiations may begin with the announcement of the selected Manufacturer.

If the contract negotiation period exceeds forty-five (45) days, or if the selected Manufacturer fails to sign the final contract within fourteen (14) days of delivery, LDH may elect to cancel the award and award the contract to the next-highest-ranked Manufacturer.

Notice of Intent to Award

The Evaluation Team will compile the scores and make a recommendation to the head of the department based on the responsive and responsible Manufacturer with the highest score. The Department will notify the successful Manufacturer and proceed to negotiate terms for final contract. Unsuccessful Manufacturers will be notified in writing accordingly.

The Department reserves the right to:

- Make multiple awards;
- Make an award without presentations by Manufacturers, or further discussion of offers received;
- Enter into a contract without further discussion of the offer submitted based on the initial offers received; or
- Contract for all or a partial list of services offered in the offer. The offers received (***except for that information appropriately designated as confidential in accordance with R.S. 44:3.2***), selection memorandum along with list of criteria used along with the weight assigned each criteria; scores of each offer considered along with overall scores of each offer considered, and a narrative justifying selection shall be made available, upon request, to all interested parties after the contract has been awarded.

The award of a contract is subject to the approval of the State.

1.24 Right to Prohibit Award

The Department reserves the right to reject any offer from, or not award a contract to, an entity in which any individual with an ownership interest of five percent or more, has been convicted of, or has entered a plea of guilty or nolo contendere to any state felony or equivalent federal felony crime committed in the solicitation or execution of a contract or SFO awarded under State laws.

1.25 Insurance Requirements for Contractors

Insurance shall be placed with insurers with an A.M. Best's rating of no less than A-. This rating requirement may be waived for Worker's Compensation coverage only.

1.25.1 Contractor's Insurance

The Contractor shall purchase and maintain for the duration of the contract insurance against claims for injuries to persons or damages to property, which may arise from or in connection with the performance of the work hereunder by the Contractor, its agents, representatives, employees or subcontractors. The cost of such insurance shall be included in the total contract amount. The Contractor shall not commence work under this contract until it has obtained all insurance required herein, including but not limited to Automobile Liability Insurance, Workers' Compensation Insurance and General Liability Insurance. Certificates of Insurance, fully executed by officers of the Insurance Company shall be filed with the Department for approval. The Contractor shall not allow any subcontractor to commence work on subcontract until all similar insurance required for the subcontractor has been obtained and approved. If so requested, the Contractor shall also submit copies of insurance policies for inspection and approval of the Department before work is commenced. Said policies shall not be canceled, permitted to expire, or be changed without thirty (30) days' written notice in advance to the Department and consented to by the Department in writing and the policies shall so provide.

1.25.2 Minimum Scope and Limits of Insurance

1.25.2.1 Workers' Compensation

Workers' Compensation insurance shall comply with the Workers Compensation law of the State of the Contractor's headquarters. Employers Liability is included with a minimum limit of \$1,000,000 per accident/per disease/per employee. If work is to be performed over water and involves maritime exposure, applicable LHWCA, Jones Act, or other maritime law coverage shall be included. A.M. Best's insurance company rating requirement may be waived for workers compensation coverage only.

Before any work is commenced, the Contractor shall obtain and maintain during the life of the contract, Workers' Compensation Insurance for all of the Contractor's employees employed to provide services under the contract. In case any work is sublet, the Contractor shall require the subcontractor similarly to provide Workers' Compensation Insurance for all the latter's employees, unless such employees are covered by the protection afforded by the Contractor. In case any class of employees engaged in work under the contract at the site of the project is not protected under the Workers' Compensation Statute, the Contractor shall provide for any such employees, and shall further provide or cause any and all subcontractors to provide Employer's Liability Insurance for the protection of such employees not protected by the Workers' Compensation Statute.

1.25.2.2 Commercial General Liability

Commercial General Liability insurance, including Personal and Advertising Injury Liability and Products and Completed Operations, shall have a minimum limit per occurrence of \$1,000,000 and a minimum general annual aggregate of \$2,000,000. The Insurance Services Office (ISO) Commercial General Liability occurrence coverage form CG 00 01 (current form approved for use in Louisiana), or equivalent, is to be used in the policy. Claims-made form is unacceptable.

The Contractor shall maintain during the life of the contract such Commercial General Liability Insurance which shall protect Contractor, the Department, and any subcontractor during the performance of work covered by the contract from claims or damages for personal injury, including accidental death, as well as for claims for property damages, which may arise from operations under the contract, whether such operations be by the Contractor or by a subcontractor, or by anyone directly or indirectly employed by either of them, or in such a manner as to impose liability to the Department. Such insurance shall name the Department as additional insured for claims arising from or as the result of the operations of the Contractor or its subcontractors.

1.25.2.3 Professional Liability (Errors and Omissions)

Professional Liability (Error & Omissions) insurance, which covers the professional errors, acts, or omissions of the Contractor, shall have a minimum limit of \$1,000,000. Claims-made coverage is acceptable. The date of the inception of the policy must be no later than the first date of the anticipated work under this contract. It shall provide coverage for the duration of this contract and shall have an expiration date no earlier than 30 days after the anticipated completion of the contract. The policy shall provide an extended reporting period of not less than 36 months from the expiration date of the policy, if the policy is not renewed.

1.25.2.4 Automobile Liability

Automobile Liability Insurance shall have a minimum combined single limit per accident of \$1,000,000. ISO form number CA 00 01 (current form approved for use in Louisiana), or equivalent, is to be used in the policy. This insurance shall include third-party bodily injury and property damage liability for owned, hired and non-owned automobiles.

Such insurance shall cover the use of any non-licensed motor vehicles engaged in operations within the terms of the contract on the site of the work to be performed thereunder, unless such coverage is included in insurance elsewhere specified.

1.25.2.5 Cyber Liability

Cyber liability insurance, including first-party costs, due to an electronic breach that compromises the State's confidential data shall have a minimum limit per occurrence of \$1,000,000. Claims-made coverage is acceptable. The date of the inception of the policy must be no later than the first date of the anticipated work under this contract. It shall provide coverage for the duration of this contract and shall have an expiration date no earlier than 30 days after the anticipated completion of the contract. The policy shall provide an extended reporting period of not less than 36 months from the expiration date of the policy, if the policy is not renewed. The policy shall not be cancelled for any reason, except non-payment of premium.

1.25.3 Deductibles and Self-Insured Retentions

Any deductibles or self-insured retentions must be declared to and accepted by the Department. The Contractor shall be responsible for all deductibles and self-insured retentions.

1.25.4 Deductibles and Self-Insured Retentions Other Insurance Provisions

1.25.4.1 Insurance Covering Special Hazards

Special hazards as determined by the Department shall be covered by rider or riders in the Commercial General Liability Insurance Policy or policies herein elsewhere required to be furnished by the Contractor, or by separate policies of insurance in the amounts as defined in any Special Conditions of the contract included therewith.

The policies are to contain, or be endorsed to contain, the following provisions:

1.25.4.2 Commercial General Liability, Automobile Liability, & Cyber Liability Coverages

The Department, its officers, agents, employees and volunteers shall be named as an additional insured as regards negligence by the contractor. ISO Forms CG 20 10 (for ongoing work) AND CG 20 37 (for completed work) (current forms approved for use in Louisiana), or equivalents, are to be used when applicable. The overage shall contain no special limitations on the scope of protection afforded to the Department.

The Contractor's insurance shall be primary as respects the Department, its officers, agents, employees and volunteers for any and all losses that occur under the contract. Any insurance or self-insurance maintained by the Department shall be excess and non-contributory of the Contractor's insurance.

1.25.4.3 Workers Compensation and Employers Liability Coverage

To the fullest extent allowed by law, the insurer shall agree to waive all rights of subrogation against the Department, its officers, agents, employees and volunteers for losses arising from work performed by the Contractor for the Department.

1.25.4.4 All Coverages

All policies must be endorsed to require 30 days written notice of cancellation to the Department. Ten-day written notice of cancellation is acceptable for non-payment of premium. Notifications shall comply with the standard cancellation provisions in the Contractor's policy. In addition, Contractor is required to notify Department of policy cancellations or reductions in limits.

The acceptance of the completed work, payment, failure of the Department to require proof of compliance, or Department's acceptance of a non-compliant certificate of insurance shall not release the Contractor from the obligations of the insurance requirements or indemnification agreement.

The insurance companies issuing the policies shall have no recourse against the Department for payment of premiums or for assessments under any form of the policies.

Any failure of the Contractor to comply with reporting provisions of the policy shall not affect coverage provided to the Department, its officers, agents, employees and volunteers.

1.25.5 Acceptability of Insurers

All required insurance shall be provided by a company or companies lawfully authorized to do business in the jurisdiction in which the Project is located. Insurance shall be placed with insurers with an A.M. Best's rating of **A- or higher**. This rating requirement may be waived for workers compensation coverage only.

If at any time an insurer issuing any such policy does not meet the minimum A.M. Best rating, the Contractor shall obtain a policy with an insurer that meets the A.M. Best rating and shall submit another Certificate of Insurance within 30 days.

1.25.6 Verification of Coverage

Contractor shall furnish the Department with Certificates of Insurance reflecting proof of required coverage. The Certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf. The Certificates are to be received and approved by the Department before work commences and upon any contract renewal or insurance policy renewal thereafter.

The Certificate Holder shall be listed as follows:

State of Louisiana
Louisiana Department of Health, Its Officers, Agents, Employees and Volunteers
628 N. 4th Street
Baton Rouge, LA 70802
Phone: (225) 342-9500
Fax: (225) 342-5568

In addition to the Certificates, Contractor shall submit the declarations page and the cancellation provision for each insurance policy. The Department reserves the right to request complete certified copies of all required insurance policies at any time.

Upon failure of the Contractor to furnish, deliver and maintain required insurance, the resulting contract, at the election of the Department, may be suspended, discontinued or terminated. Failure of the Contractor to purchase and/or maintain any required insurance shall not relieve the Contractor from any liability or indemnification under the contract.

1.25.7 Subcontractors

Contractor shall include all subcontractors as insureds under its policies OR shall be responsible for verifying and maintaining the Certificates provided by each subcontractor. Subcontractors shall be subject to all the requirements stated herein. The Department reserves the right to request copies of subcontractor's Certificates at any time.

1.25.8 Workers' Compensation Indemnity

In the event Contractor is not required to provide or elects not to provide workers' compensation coverage, the parties hereby agree that Contractor, its owners, agents and employees will have no cause of action against, and will not assert a claim against, the State of Louisiana, its departments, agencies, agents and employees as an employer, whether pursuant to the Louisiana Workers Compensation Act or otherwise, under any circumstance. The parties also hereby agree that the State of Louisiana, its

departments, agencies, agents and employees shall in no circumstance be, or considered as, the employer or statutory employer of Contractor, its owners, agents and employees. The parties further agree that Contractor is a wholly independent contractor and is exclusively responsible for its employees, owners, and agents. Contractor hereby agrees to protect, defend, indemnify and hold the State of Louisiana, its departments, agencies, agents and employees harmless from any such assertion or claim that may arise from the performance of the resulting contract.

1.26 Indemnification and Limitation of Liability

Neither party shall be liable for any delay or failure in performance beyond its control resulting from acts of God or force majeure. The parties shall use reasonable efforts to eliminate or minimize the effect of such events upon performance of their respective duties under the resulting Contract.

Contractor shall be fully liable for the actions of its agents, employees, partners or subcontractors and shall fully indemnify and hold harmless the State and its Authorized Users from suits, actions, damages and costs of every name and description relating to personal injury and damage to real or personal tangible property caused by Contractor, its agents, employees, partners or subcontractors, without limitation; provided, however, that the Contractor shall not indemnify for that portion of any claim, loss or damage arising hereunder due to the negligent act or failure to act of the State. If applicable, Contractor will indemnify, defend and hold the State and its Authorized Users harmless, without limitation, from and against any and all damages, expenses (including reasonable attorneys' fees), claims, judgments, liabilities and costs which may be finally assessed against the State in any action for infringement of a United States Letter Patent with respect to the Products furnished, or of any copyright, trademark, trade secret or intellectual property right, provided that the State shall give the Contractor: (i) prompt written notice of any action, claim or threat of infringement suit, or other suit, (ii) the opportunity to take over, settle or defend such action, claim or suit at Contractor's sole expense, and (iii) assistance in the defense of any such action at the expense of Contractor. Where a dispute or claim arises relative to a real or anticipated infringement, the State or its Authorized Users may require Contractor, at its sole expense, to submit such information and documentation, including formal patent attorney opinions, as the Department shall require.

The Contractor shall not be obligated to indemnify that portion of a claim or dispute based upon: i) Authorized User's unauthorized modification or alteration of a Product, Material or Service; ii) Authorized User's use of the Product in combination with other products not furnished by Contractor; iii) Authorized User's use in other than the specified operating conditions and environment.

In addition to the foregoing, if the use of any item(s) or part(s) thereof shall be enjoined for any reason or if Contractor believes that it may be enjoined, Contractor shall have the right, at its own expense and sole discretion as the Authorized User's exclusive remedy to take action in the following order of precedence: (i) to procure for the State the right to continue using such item(s) or part (s) thereof, as applicable; (ii) to modify the component so that it becomes non-infringing equipment of at least equal quality and performance; or (iii) to replace said item(s) or part(s) thereof, as applicable, with non-infringing components of at least equal quality and performance, or (iv) if none of the foregoing is commercially reasonable, then provide monetary compensation to the State up to the dollar amount of the Contract.

For all other claims against the Contractor where liability is not otherwise set forth in the Contract as being "without limitation", and regardless of the basis on which the claim is made, Contractor's liability for direct damages, shall be the greater of \$100,000, the dollar amount of the Contract, or two (2) times the charges rendered by the Contractor under the Contract. Unless otherwise specifically enumerated herein or in the work order mutually agreed between the parties, neither party shall be liable to the other for special, indirect or consequential damages, including lost data or records (unless the Contractor is required to back-up the data or records as part of the work plan), even if the party has been advised of the possibility of such damages. Neither party shall be liable for lost profits, lost revenue or lost institutional operating savings.

The State and Authorized User may, in addition to other remedies available to them at law or equity and upon notice to the Contractor, retain such monies from amounts due Contractor, or may proceed against the performance and payment bond, if any, as may be necessary to satisfy any claim for damages, penalties, costs and the like asserted by or against them.

1.27 Termination

1.27.1 Termination of the Contract for Cause

The State may terminate the resulting Contract for cause based upon the failure of the Contractor to comply with the terms and/or conditions of the Contract; provided the State shall give the Contractor written notice specifying the Contractor's failure. If within thirty (30) calendar days after receipt of such notice, the Contractor shall not have either corrected such failure or, in the case of failure which cannot be corrected in thirty (30) calendar days, begun in good faith to correct said failure and thereafter proceeded diligently to complete such correction, then the State may, at its option, place the Contractor in default and the Contract shall terminate on the date specified in such notice. Failure to perform within the time agreed upon in the contract may constitute default and may cause cancellation of the contract.

Contractor may exercise any rights available to it under Louisiana law to terminate for cause upon the failure of the State to comply with the terms and conditions of this contract provided that the Contractor shall give the State written notice specifying the State department's failure and a reasonable opportunity for the State to cure the defect.

1.27.2 Termination of the Contract for Convenience

The State may terminate the Contract at any time without penalty by giving thirty (30) calendar days' written notice to the Contractor of such termination or negotiating with the Contractor an effective date. Contractor shall be entitled to payment for deliverables in progress, to the extent work has been performed satisfactorily.

1.28 Assignment

No contractor shall assign any interest in this contract by assignment, transfer, or novation, without prior written consent of the State. This provision shall not be construed to prohibit the contractor from assigning to a bank, trust company, or other financial institution any money due or to become due from approved contracts without such prior written consent. Notice of any such assignment or transfer shall be furnished promptly to the State.

Any assignment, pledge, joint venture, hypothecation of right or responsibility to any person, firm or corporation should be fully explained and detailed in the offer. Information as to the experience and qualifications of proposed subcontractors or joint ventures should be included in the offer. In addition, written commitments from any subcontractors or joint ventures should be included as part of the offer. All assignments must be approved of by the Department.

1.29 Right to Audit

The State Legislative Auditor, internal auditors of the Division of Administration, department auditors, and if applicable, federal auditors shall be entitled to audit the books and records of a contractor or any subcontractor under any negotiated contract or subcontract to the extent that such books and records relate to the performance of such contract or subcontract. Such books and records shall be maintained by the contractor for a period of five (5) years from the date of the termination of the prime contract and by the subcontractor for a period of five (5) years from the date of the termination of the subcontract.

Civil Rights Compliance

The contractor agrees to abide by the requirements of the following as applicable: Title VI of the Civil Rights Act of 1964 and Title VII of the Civil Rights Act of 1964, as amended by the Equal Employment Opportunity Act of 1972, Federal Executive Order 11246 as amended, the Rehabilitation Act of 1973, as amended, the Vietnam Era Veteran's Readjustment Assistance Act of 1974, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, the Fair Housing Act of 1968 as amended, and contractor agrees to abide by the requirements of the Americans with Disabilities Act of 1990.

Contractor agrees not to discriminate in its employment practices and will render services under any resulting contract without regard to race, color, religion, sex, sexual orientation, national origin, veteran status, political affiliation, disability, or age in any matter relating to employment. Any act of discrimination committed by Contractor, or failure to comply with these statutory obligations when applicable shall be grounds for termination of the resulting contract.

1.30 Record Ownership

All records, reports, documents, or other material related to any contract resulting from this SFO and/or obtained or prepared by the Contractor in connection with the performance of the services contracted for shall become the property of the Department and shall, upon request, be returned by the Contractor to the Department, at the Contractor's expense, at termination or expiration of the contract.

1.31 Entire Agreement/ Order of Precedence

Any resulting contract, together with the SFO and addenda issued thereto by the Department, the offer submitted by the Contractor in response to the Department's SFO, and any exhibits or attachments specifically incorporated herein by reference, shall constitute the entire agreement between the parties with respect to the subject matter.

In the event of any inconsistent or incompatible provisions, any resulting signed agreement (excluding the SFO and the Contractor's offer) shall take precedence, followed by the provisions of the SFO, and then by the terms of the Contractor's offer.

1.32 Contract Modifications

No amendment or variation of the terms of the resulting contract shall be valid unless made in writing, signed by the parties and approved as required by law. No oral understanding or agreement not incorporated in the contract shall be binding on any of the parties.

1.33 Substitution of Personnel

The Contractor's personnel assigned to this Contract shall not be replaced without the prior written consent of the Department. Such consent shall not be unreasonably withheld or delayed provided an equally qualified replacement is offered. If any State or Contractor personnel become unavailable due to resignation, illness, or other factors, excluding assignment to a project outside this contract, outside of the Department's or Contractor's reasonable control the Department or the Contractor shall be responsible for providing an equally qualified replacement in time to avoid delays in completing tasks. The contractor will make every reasonable attempt to assign the personnel listed in his offer.

1.34 Governing Law

This contract shall be governed by and interpreted in accordance with the laws of the State of Louisiana, except for its provisions regarding conflict of laws. Venue of any action brought with regard to this contract shall be in the Nineteenth Judicial District Court, Parish of East Baton Rouge, State of Louisiana.

1.35 Claims or Controversies

Any claim or controversy arising out of the contract shall be resolved in accordance with the provisions of La.R.S. 39:1672.2-1672.4.

1.35.1 Code of Ethics

Proposers shall be responsible for ensuring that there will be no conflict or violation of the Louisiana Ethics Code if their company is awarded the contract. The Louisiana Board of Ethics shall be the only entity that can officially rule on ethical issues. Notwithstanding, any potential conflict of interest that is known or should reasonably be known by a Proposer as it relates to the SFO should be immediately reported to the Department by Proposer.

The contractor acknowledges that Chapter 15 of Title 42 of the Louisiana Revised Statutes (R.S. 42:1101 et seq., Code of Governmental Ethics) applies to the Contracting Party in the performance of services called for in this contract. The contractor agrees to notify the State immediately if potential violations of the Code of Governmental Ethics arise at any time during the term of this contract

1.36 Corporate Requirements

If the contractor is a corporation, the following requirements must be met prior to execution of the contract:

If the contractor is a for-profit corporation whose stock is not publicly traded, the contractor shall ensure that a disclosure of ownership form has been properly filed with the Secretary of State of Louisiana.

If the contractor is a corporation not incorporated under the laws of the State of Louisiana-the contractor must obtain a Certificate of Authority pursuant to R.S. 12:301-302 from the Louisiana Secretary of State.

The contractor must provide written assurance to the Department from contractor's legal counsel that the contractor is not prohibited by its articles of incorporation, bylaws or the laws under which it is incorporated from performing the services required under the contract.

1.37 Performance Requirements

Performance under any contract arising out of this SFO will be ongoing for the duration of the term and will require constant evaluation of the manufacturing and supply chain for DAAs, communications regarding cost and, potentially, depending on the payment mechanism selected, rebate calculations, as well as evaluation of the complementary services provided thereunder by the Contractor.

1.38 Performance Measurement/Evaluation/Monitoring Plan

The State reserves the right to introduce performance measurement, evaluation and monitoring plans with the selected manufacturer(s) during the negotiation process and to implement such plans to ensure satisfactory performance under the resulting agreements.

1.39 Veteran and Hudson Initiative Programs Reporting Requirements

During the term of the contract and at expiration, the Contractor will be required to report Veteran-Owned and Service-Connected Disabled Veteran-Owned and Hudson Initiative small entrepreneurship subcontractor participation and the dollar amount of each.

Veteran-Owned and Service-Connected Small Entrepreneurships (Veteran Initiative) And Louisiana Initiative

For Small Entrepreneurships (Hudson Initiative) Programs

The State of Louisiana Veteran and Hudson Initiatives are designed to provide additional opportunities for Louisiana-based small entrepreneurships (sometimes referred to as LaVet's and SE's respectively) to participate in contracting and procurement with the State. A certified Veteran-Owned and Service-Connected Disabled Veteran-Owned small entrepreneurship (LaVet) and a Louisiana Initiative for Small Entrepreneurships (Hudson Initiative) small entrepreneurship are businesses that have been certified by the Louisiana Department of Economic Development. All eligible vendors are encouraged to become certified. Qualification requirements and online certification are available at:

<https://smallbiz.louisianaeconomicdevelopment.com>.

If a Proposer is not a certified small entrepreneurship as described herein but plans to use certified small entrepreneurship(s), Proposer shall include in their offer the names of their certified Veteran Initiative or Hudson Initiative small entrepreneurship subcontractor(s), a description of the work each will perform, and the dollar value of each subcontract.

During the term of the contract and at expiration, the Contractor will also be required to report Veteran-Owned and Service-Connected Disabled Veteran-Owned and Hudson Initiative small entrepreneurship subcontractor or distributor participation and the dollar amount of each.

In SFO's requiring the compliance of a good faith subcontracting plan, the State may require Proposers to submit information on their business relationships and arrangements with certified LaVet or Hudson Initiative subcontractors at the time of offer review. Agreements between a Proposer and a certified LaVet or Hudson Initiative subcontractor in which the certified LaVet or Hudson Initiative subcontractor promises not to provide subcontracting quotations to other Manufacturers shall be prohibited.

If performing its evaluation of offers, the State reserves the right to require a non-certified Manufacturer to provide documentation and information supporting a good faith subcontracting plan. Such proof may include contracts between Proposer and certified Veteran Initiative and/or Hudson Initiative subcontractor(s).

If a contract is awarded to a Proposer who proposed a good faith subcontracting plan, the using department, the Louisiana Department of Economic Development (LED) may audit Contractor to determine whether Contractor has complied in good faith with its subcontracting plan. The Contractor must be able to provide supporting documentation (i.e., phone logs, fax transmittals, letter, e-mails) to demonstrate its good faith subcontracting plan was followed. If it is determined at any time by the using department or LED that the Contractor did not in fact perform in good faith its subcontracting plan, the contract award or the existing contract may be terminated.

The statutes (La. R.S. 39:2171 et. seq.) concerning the Veteran Initiative may be viewed at:

[http://www.legis.la.gov/Legis/Law.aspx?d=671504.](http://www.legis.la.gov/Legis/Law.aspx?d=671504)

The statutes (La. R.S. 39:2001 et. seq.) concerning the Hudson Initiative may be viewed at:

[http://www.legis.la.gov/Legis/Law.aspx?d=96265.](http://www.legis.la.gov/Legis/Law.aspx?d=96265)

The rules for the Veteran Initiative (LAC 19: VII. Chapters 11 and 15) and for the Hudson Initiative (LAC 19: VIII Chapters 11 and 13) may be viewed at:

[http://www.doa.la.gov/pages/osp/se/secv.aspx.](http://www.doa.la.gov/pages/osp/se/secv.aspx)

A current list of certified Veteran-Owned and Service-Connected Disabled Veteran-Owned and Hudson Initiative small entrepreneurship may be obtained from the Louisiana Economic Development Certification System at: [https://smallbiz.louisianaeconomicdevelopment.com.](https://smallbiz.louisianaeconomicdevelopment.com)

Additionally, a list of Hudson and Veteran Initiative small entrepreneurship, which have been certified by the Louisiana Department of Economic Development and who have opted to register in the State of Louisiana LaGov Supplier Portal:

[https://lagoverpvendor.doa.louisiana.gov/irj/portal/anonymous?guest_user=self_reg.](https://lagoverpvendor.doa.louisiana.gov/irj/portal/anonymous?guest_user=self_reg)

This may be accessed from the State of Louisiana Procurement and Contract (LaPAC) Network:

[https://wwwcfprd.doa.louisiana.gov/OSP/LaPAC/vendor/VndPubMain.cfm.](https://wwwcfprd.doa.louisiana.gov/OSP/LaPAC/vendor/VndPubMain.cfm)

When using this site, determine the search criteria (i.e. alphabetized list of all certified vendors, by commodities, etc.) and select SmallE, VSE, or DVSE.

CERTIFICATION STATEMENT

The undersigned hereby acknowledges she/he has read and understands all requirements and specifications of the Solicitation for Offers (SFO), including attachments.

OFFICIAL CONTACT: The State requests that the Proposer designate one person to receive all documents and the method in which the documents are best delivered. Identify the Contact name and fill in the information below: (Print Clearly)

Date	
Official Contact Name	
Email Address	
Fax Number with Area Code	
Telephone Number	
Street Address	
City, State, and Zip	

Proposer certifies that the above information is true and grants permission to the Department to contact the above-named person or otherwise verify the information I have provided.

By its submission of this offer and authorized signature below, Proposer certifies that:

1. The information contained in its response to this SFO is accurate;
2. Proposer r complies with each of the mandatory requirements listed in the SFO and will meet or exceed the functional and technical requirements specified therein;
3. Proposer accepts the procedures, evaluation criteria, mandatory contract terms and conditions, and all other administrative requirements set forth in this SFO.
4. Offers are valid for *90* calendar days from the date of Offeror's signature below;
5. Proposer understands that if selected as the successful Offeror, he/she will have 45 calendar days from the date of delivery of initial contract in which to complete contract negotiations, if any, and execute the final contract document. The Department has the option to waive this deadline if actions or inactions by the Department cause the delay.
6. Proposer certifies, by signing and submitting an offer for \$25,000 or more, that their company, any subcontractors, or principals are not suspended or debarred by the General Services Administration

(GSA) in accordance with the requirements in OMB Circular A-133. (A list of parties who have been suspended or debarred can be viewed via the internet at <https://www.sam.gov>).

7. Proposer understands that, if selected as a contractor, the Louisiana Department of Revenue must determine that it is current in the filing of all applicable tax returns and reports and in payment of all taxes, interest, penalties, and fees owed to the state and collected by the LDR. Manufacturer shall comply with R.S. 39:1624(A)(10) by providing its seven-digit LDR account number in order for tax payment compliance status to be verified.
8. Proposer further acknowledges its understanding that issuance of a tax clearance certificate by LDR is a necessary precondition to the approval of any contract. The contracting department reserves the right to withdraw its consent to any contract without penalty and proceed with alternate arrangements, should a prospective contractor fail to resolve any identified outstanding tax compliance discrepancies with the LDR within seven (7) days of such notification.
9. In preparing its response, the Manufacturer has considered all offers submitted from qualified, potential subcontractors and suppliers, and has not, in the solicitation, selection, or commercial treatment of any subcontractor or supplier, refused to transact or terminate business activities, or take any other action intended to limit commercial relations, with a person or entity that is engaging in commercial transactions in Israel or Israeli-controlled territories, with the specific intent to accomplish a boycott or divestment of Israel. Proposer also has not retaliated against any person or other entity for reporting such refusal, termination, or commercially limiting action. The State reserves the right to reject the response of the Proposer if this certification is subsequently determined to be false, and to terminate any contract awarded based on such a false response.

Authorized Signature: _____

Original Signature Only: Electronic or Photocopy Signature are NOT Allowed

Print Name: _____

Title: _____

Rev 09/2013

HIPAA Business Associate Addendum

This HIPAA Business Associate Addendum is hereby made a part of this contract in its entirety as Attachment _____ to the contract.

1. The Louisiana Department of Health (“LDH”) is a Covered Entity, as that term is defined herein, because it functions as a health plan and as a health care provider that transmits health information in electronic form.
2. Contractor is a Business Associate of LDH, as that term is defined herein, because contractor either: (a) creates, receives, maintains, or transmits PHI for or on behalf of LDH; or (b) provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services for LDH involving the disclosure of PHI.
3. Definitions: As used in this addendum –
 - A. The term “HIPAA Rules” refers to the federal regulations known as the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, found at 45 C.F.R. Parts 160 and 164, which were originally promulgated by the U. S. Department of Health and Human Services (DHHS) pursuant to the Health Insurance Portability and Accountability Act (“HIPAA”) of 1996 and were subsequently amended pursuant to the Health Information Technology for Economic and Clinical Health (“HITECH”) Act of the American Recovery and Reinvestment Act of 2009.
 - B. The terms “Business Associate”, “Covered Entity”, “disclosure”, “electronic protected health information” (“electronic PHI”), “health care provider”, “health information”, “health plan”, “protected health information” (“PHI”), “subcontractor”, and “use” have the same meaning as set forth in 45 C.F.R. § 160.103.
 - C. The term “security incident” has the same meaning as set forth in 45 C.F.R. § 164.304.
 - D. The terms “breach” and “unsecured protected health information” (“unsecured PHI”) have the same meaning as set forth in 45 C.F.R. § 164.402.
4. Contractor and its agents, employees and subcontractors shall comply with all applicable requirements of the HIPAA Rules and shall maintain the confidentiality of all PHI obtained by them pursuant to this contract and addendum as required by the HIPAA Rules and by this contract and addendum.
5. Contractor shall use or disclose PHI solely: (a) for meeting its obligations under the contract; or (b) as required by law, rule or regulation (including the HIPAA Rules) or as otherwise required or permitted by this contract and addendum.
6. Contractor shall implement and utilize all appropriate safeguards to prevent any use or disclosure of PHI not required or permitted by this contract and addendum, including administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of LDH.

7. In accordance with 45 C.F.R. § 164.502(e)(1)(ii) and (if applicable) § 164.308(b)(2), contractor shall ensure that any agents, employees, subcontractors or others that create, receive, maintain, or transmit PHI on behalf of contractor agree to the same restrictions, conditions and requirements that apply to contractor with respect to such information, and it shall ensure that they implement reasonable and appropriate safeguards to protect such information. Contractor shall take all reasonable steps to ensure that its agents', employees' or subcontractors' actions or omissions do not cause contractor to violate this contract and addendum.
8. Contractor shall, within three (3) days of becoming aware of any use or disclosure of PHI, other than as permitted by this contract and addendum, report such disclosure in writing to the LDH Contract Monitor. Disclosures which must be reported by contractor include, but are not limited to, any security incident, any breach of unsecured PHI, and any "breach of the security system" as defined in the Louisiana Database Security Breach Notification Law, La.R.S. 51:3071 *et seq.* At the option of LDH, any harm or damage resulting from any use or disclosure which violates this contract and addendum shall be mitigated, to the extent practicable, either: (a) by contractor at its own expense; or (b) by LDH, in which case contractor shall reimburse LDH for all expenses that LDH is required to incur in undertaking such mitigation activities.
9. To the extent that contractor is to carry out one or more of LDH's obligations under 45 C.F.R. Part 164, Subpart E, contractor shall comply with the requirements of Subpart E that apply to LDH in the performance of such obligation(s).
10. Contractor shall make available such information in its possession which is required for LDH to provide an accounting of disclosures in accordance with 45 CFR § 164.528. In the event that a request for accounting is made directly to contractor, contractor shall forward such request to LDH within two (2) days of such receipt. Contractor shall implement an appropriate record keeping process to enable it to comply with the requirements of this provision. Contractor shall maintain data on all disclosures of PHI for which accounting is required by 45 CFR § 164.528 for at least six (6) years after the date of the last such disclosure.
11. Contractor shall make PHI available to LDH upon request in accordance with 45 CFR § 164.524.
12. Contractor shall make PHI available to LDH upon request for amendment and shall incorporate any amendments to PHI in accordance with 45 CFR § 164.526.
13. Contractor shall make its internal practices, books, and records relating to the use and disclosure of PHI received from or created or received by contractor on behalf of LDH available to the Secretary of the U. S. DHHS for purposes of determining LDH's compliance with the HIPAA Rules.
14. Contractor shall indemnify and hold LDH harmless from and against any and all liabilities, claims for damages, costs, expenses and attorneys' fees resulting from any violation of this addendum by contractor or by its agents, employees or subcontractors, without regard to any limitation or exclusion of damages provision otherwise set forth in the contract.
15. The parties agree that the legal relationship between LDH and contractor is strictly an independent contractor relationship. Nothing in this contract and addendum shall be deemed to create a joint venture, department, partnership, or employer-employee relationship between LDH and contractor.

16. Notwithstanding any other provision of the contract, LDH shall have the right to terminate the contract immediately if LDH determines that contractor has violated any provision of the HIPAA Rules or any material term of this addendum.
17. At the termination of the contract, or upon request of LDH, whichever occurs first, contractor shall return or destroy (at the option of LDH) all PHI received or created by contractor that contractor still maintains in any form and retain no copies of such information; or if such return or destruction is not feasible, contractor shall extend the confidentiality protections of the contract to the information and limit further uses and disclosure to those purposes that make the return or destruction of the information infeasible.

Regional Map

