Louisiana's Hepatitis C Subscription Model and Solicitation for Offers

To: John Bel Edwards

From: Rebekah Gee

Date: January 9, 2019

Brief: Louisiana's Hepatitis C Subscription Model and Solicitation for Offers

SUMMARY

Louisiana is facing a public health crisis caused by Hepatitis C, the deadliest infectious disease in the US. This crisis can be addressed by providing curative treatment to those who are infected. Unfortunately, at current prices, only a tiny fraction of those who need treatment receive it. Faced with one of the nation's worst epidemics and State budget limitations, LDH is pursuing an innovative Subscription Model designed to help end the epidemic. This model, accomplished using a competitive Solicitation of Offers (SFO) process, will create a public/private partnership with a drug manufacturer that enable the State to pursue elimination of Hepatitis C as a public health epidemic in Louisiana. Through this Subscription Model, LDH plans to treat over 10,000 Medicaid and incarcerated individuals by the end of 2020.

BACKGROUND

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. At least 90,900 Louisianans are currently infected with Hepatitis C, a disproportionate number of whom are low-income and/or incarcerated. About 39,000 people in Louisiana's Medicaid program and state prisons are known to be chronically infected. 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 at rates as high as 99%. However, the high cost of treatment prohibits the State from providing this cure to many patients, including those in Medicaid. Last year, less than 3% of infected Medicaid beneficiaries received treatment despite the State spending more than $30 million on DAAs. This limited coverage approach reflects the high costs of DAA treatment and limited State resources.

Transformational change is required to have any chance of slowing and, ultimately, reversing this growing epidemic. As a result, the Department is pursuing an innovative arrangement, called a Subscription Model, that will enable the State to expand treatment to all infected individuals in Medicaid and corrections without increasing expenditures on DAAs beyond 2018 levels.

THE SUBSCRIPTION MODEL

Under the Subscription Model, LDH will enter into an agreement with a manufacturer to utilize their DAA for the treatment of Hepatitis C in the referenced populations. This arrangement provides unlimited access to DAAs for 5 years for all Louisianans enrolled in Medicaid or

incarcerated. The total cost will be equal to or less than what the State and federal governments spent on DAAs for these populations in 2018, no matter how much treatment is provided.

This Subscription Model effectively caps the State's spending on Hepatitis C drugs and creates an incentive to treat as many infected people as possible, regardless of disease progression. For the drug manufacturer, this model guarantees fixed revenue for the term of the contract from a large volume payer, protects market share against an increasingly competitive landscape, and enables the manufacturer to expand their reach into populations that otherwise will not receive treatment.

Subscription Model Payment Arrangement

Annual expenditures under the model will be 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 2018, around $35 million. While the total expenditure combines the Medicaid and corrections DAA spend, the Subscription Model will be funded through two separate agreements.

In Medicaid, the manufacturer will provide rebates to the State via Supplemental Rebate Agreements, effectively limiting the Total State Spend for DAAs in Medicaid. SRAs are agreements established between one or more state Medicaid programs and a drug manufacturer to negotiate lower prices than those set forth in DHHS's national rebate agreement. In this case, Louisiana Medicaid will enter into an SRA that yields a set annual revenue for the manufacturer at or below the State Fiscal Year 2018 Medicaid spend for DAAs. This can 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.

In corrections, the manufacturer will use 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.[1] Negotiations with a 340B covered entity are exempt from this requirement, protecting the manufacturer contracting with the State from affecting their 'best price' through participation in the Subscription Model. This can be achieved by having Lallie Kemp, a 340B covered entity providing clinical services to inmates on behalf of the DOC, purchase DAAs at a best price-exempt negotiated cost. Much like the SRA in Medicaid, the price for DAA for corrections would be adjusted over time to ensure it does not exceed the 2018 Total State Spend.

[1] 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.

Selecting a DAA Manufacturer – The Solicitation for Offers

LDH will competitively select one DAA manufacturer with whom to enter into the 5-year Subscription Model agreement.[2] Competitive selection is preferred to achieve the best possible arrangement, meet the federal Medicaid program's requirements, and mitigate the risk of legal protests from non-selected manufacturers. SFO will be released on **January 10, 2019**. The SFO is not directly tied to any funding but obligates the State and a manufacturer to negotiate a contract establishing the terms of the Subscription Model.[3] The manufacturer will be selected based on the value of their bid, the efficacy of their DAA across these populations, and the potential benefit of any complementary services they offer to advance the State's broader Hepatitis C Elimination Program goals. An overview of the State's Hepatitis C Elimination Program (see below) is included in the SFO to encourage bidders to augment their bid on the Subscription Model contract by proposing complementary services. Selection of the manufacturer is set for **April 15, 2019**, with a firm Subscription Model go-live date of **July 1, 2019**.

Louisiana Hepatitis C Elimination Program

The Subscription Model is not enough on its own to meet LDH's goal of curing more than 10,000 Louisianans by the end of 2020. LDH will also implement complementary strategies in parallel with the Subscription Model to ensure the unlimited supply of DAAs reach the intended populations. The additional strategies comprising the Hepatitis C Elimination Program are:

- Expand Provider Capacity to Treat Hepatitis C – Expanding hepatitis C treatment beyond specialty care by training primary care providers to diagnose and treat hepatitis C, as well as refer advanced liver disease, cancer, and substance use disorder to specialists as appropriate;
- Educate Public on Availability of Cure and Mobilize Priority Populations for Screenings –To mobilize priority populations to get screened and treated, public messaging must be developed around: the risk factors for contracting hepatitis C, access to screening, the importance of treating hepatitis C before symptoms appear, and the State's unprecedented access to DAAs under the Subscription Model.
- 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 at increased risk of infection such as people who inject drugs. Health care providers across the State will screen priority populations to ensure all individuals with hepatitis C are linked to care for treatment;
- Strengthen HCV Surveillance to Link Persons Previously Diagnosed to Treatment – LDH's existing hepatitis C surveillance system will be upgraded to support the timely identification of individuals with chronic hepatitis C infections;

[2] While the SFO leaves open the possibility that one of the manufacturers might opt to partner with another in order to provide the most comprehensive virologic coverage, in order to streamline the operation of the subscription model, one of the manufacturers will be designated as the prime contractor and will enter its own subcontract with the second manufacturer.

[3] See attached Draft, Excerpted SFO.

- Implement Harm Reduction and Complementary Treatment Strategies – Strategies to prevent new or reinfections must also be employed, including expanded access to syringe service programs and behavioral and medication assisted treatment for opioid use disorder;
- Extend Elimination Efforts to All Populations Within the State – Many Louisianans infected with hepatitis C are neither Medicaid beneficiaries nor incarcerated. To truly achieve statewide elimination, the State will work with new and existing partners, including commercial insurers, health systems, and entities serving the uninsured through other appropriate mechanisms.

LOUISIANA DEPARTMENT OF HEALTH

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

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 $30,000,000.00, and the Total State Spend on hepatitis C medications in the Corrections population, estimated to be $5,000,000.00, for State Fiscal Year 2018; (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.
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 Offerer	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 abstention 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	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. 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. 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.
340b Patient Definition	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. An individual is a patient of a 340B covered entity (except for State-operated or funded AIDS drug purchasing assistance programs) only if: • 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 contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and • 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.

1.5 Schedule of Events

Event	**Date**

SFO advertised in newspapers	January 10, 2019
Deadline for receipt of written inquiries	January 28, 2109 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
30 Day Negotiation Period Begins	May 1, 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. 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.