



**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**

Pharmaceutical Manufacturers' Written Questions & Answers

1. How many people living with HCV are estimated to be enrolled in LA Medicaid? Covered by Louisiana Department of Corrections ("DOC")?

The State does not know the precise number of current Medicaid beneficiaries or incarcerated individuals who have chronic hepatitis C. Publicly available prevalence estimates for these populations are known to be imprecise and fail to account for higher incidence of disease within vulnerable populations. The State is currently evaluating its existing hepatitis C prevalence data, and the systems from which such data is obtained, in order to more fully develop an accurate and precise count of individuals with hepatitis C in these populations. Population level screening for hepatitis C is not occurring in either Medicaid or Corrections which further limits the State's ability to provide an accurate count. Subject to the preceding caveats, the State's best estimate of the number of current Medicaid enrollees with chronic hepatitis C is roughly 34,000. In addition, and subject to the same caveats, the State's best estimate of the number of individuals currently incarcerated at DOC facilities who have chronic hepatitis C is roughly 5,000.

2. How many patients have been treated annually in recent years, and how many patients does the state expect to treat per year over the next five years? What was the quarterly utilization, separately for Medicaid and DOC, for each of the past eight calendar quarters, through Q4 2018?

Year/Quarter	Distinct Recipients Treated with Direct-Acting Agents (DAA), Categorized by Quarter of DAA Initiation	Count of All Direct-Acting Agent (DAA) Claims, Categorized by Quarter of Prescription Fill Date
2017Q1 (Jan-Mar 2017)	182	344
2017Q2 (Apr-Jun 2017)	185	483
2017Q3 (Jul-Sep 2017)	158	519
2017Q4 (Oct-Dec 2017)	158	505
CY2017 Total	683	1,851
2018Q1 (Jan-Mar 2018)	204	509
2018Q2 (Apr-Jun 2018)	282	672
2018Q3 (Jul-Sep 2018)	329	877
2018Q4 (Oct-Dec 2018)	326	871
CY2018 Total	1,141	2,929

- a. In what types of facilities were these patients treated, and where do you anticipate Medicaid beneficiaries living with HCV will be treated in the future? More specifically, is the State able to share county-level HCV treatment data in Medicaid, or HCV treatment data on sites of care such as FQHCs vs. outpatient specialty clinics vs. hospitals?

The patients above were treated in outpatient settings. Most prescriptions were dispensed in the greater New Orleans area.

- b. What specific pharmacies dispensed HCV medication for Medicaid patients (please quantify the number of fills per pharmacy, to the extent possible)?

Pharmacies	Number
< 20 claims	27
21-50 claims	6
51-100 claims	2
> 100 claims	3

- c. Would a successful offer be required to make HCV drugs available through all Medicaid-participating pharmacies or could a successful offer include distribution through a combination of a limited retail pharmacy network and mail order pharmacy?

Louisiana is an “any willing provider” state. A successful offer will make DAAs available through all Medicaid-participating pharmacies.

3. Can Louisiana share, epidemiology data for the Medicaid and Corrections populations, respectively (i.e., genotype distribution, fibrosis scores, non-cirrhotic/cirrhotic/decompensated cirrhosis, concomitant diseases especially HIV infection, concomitant medications in patients living with HCV, liver transplant, prior HCV treatment, etc.)?

The State does not have access to this data for either population. In response, the State would refer you to publicly available resources for estimating these data including but not limited to the Center for Disease Control’s HepVu site located at <https://hepvu.org/state/louisiana/> and the National Health and Nutrition Examination Survey (NHANES).

4. What is the estimated proportion of the Louisiana DOC population that has been screened for HCV, what proportion of those have been diagnosed with chronic HCV, and what proportion of those patients have not yet received treatment?

DOC does not currently conduct population screening for hepatitis C. Inmates are only screened if they present with symptoms or risk factors suggesting the possibility of infection or enter the prison system with knowledge of their hepatitis C infection. DOC estimates that there are about 1,600 individuals known to have chronic hepatitis C who are currently incarcerated within DOC facilities.

5. In the example pricing model described on page 7 of the SFO, would the state pay the manufacturer an amount equal to WAC or WAC less federally mandated rebates until the budget cap has been met? More specifically, page 7 of the SFO indicates that “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”, which is estimated at \$30M (as stated on page 1). However, page 7 further states, “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.”

The example pricing model set forth on page 7 of the SFO is solely illustrative; the State cannot guarantee any set annual revenue for the successful DAA manufacturer. While Total State Spend is defined in the SFO as the State’s total pre-rebate annual DAA spend in State Fiscal Year 2018, the State intends to enter into an SRA that will cap Medicaid expenditures at or below the State Fiscal Year 2018 spend for DAAs after rebates. The State Fiscal Year 2018 Medicaid spend for DAAs is estimated at \$30M before rebates.

- a) Assuming a hypothetical \$25,000 Average Manufacturer Price (AMP) for a DAA, would the \$30M Medicaid cap mean that the cost per patient treated would be \$19,225 (\$25,000-23.1% mandatory rebate), effectively allowing for an annual

treatment cap of 1,560 patients (\$30,000,000 divided by \$19,225) before the 100% supplemental rebate would be in effect (assuming the Medicaid best price for the drug does not result in a mandatory rebate greater than the 23.1% default)? If not, please explain how the example described on page 7 would differ from this description.

The subscription model is not intended to cap the number of individuals treated; rather, the model is intended to cap the State's annual Medicaid expenditure for DAAs at or below the State Fiscal Year 2018 Medicaid expenditure for DAAs.

b) On page 7, the SRO states, "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."

i. For Medicaid, why should the price for the DAA purchases change over time? Is that due to any potential changes in Best Price?

The price for the DAA need not change over time; however, the supplemental rebate should change with utilization to ensure the State's annual Medicaid expenditure for DAAs does not exceed the cap.

ii. For Corrections, should the manufacturer expect to submit an offer that outlines the terms on a per product basis, not to exceed \$5M annually, and any utilization above that cap would be at \$0 cost to the state? If a per-product price is accepted by the State for the Corrections population, how do you expect the price for the DAA purchases could change over time?

In the example in the SFO, once the cap is hit, the 340B price would be reduced to \$0.01 per unit.

6. The Medicaid pricing model on page 7 is described as an "example." Would you consider different models, if the model provides unlimited access to HCV DAAs and the HCV spend is limited to no more than the state's 2018 Medicaid spend for DAAs?

a) More specifically, the proposal describes a spending cap model whereby the state will reimburse prescriptions up to a specified threshold. Is the state willing to consider a subscription model that involves an upfront annual payment to the manufacturer for a specific duration in return for unlimited use in the populations covered by the proposal?

As noted in the SFO, the State requires all responding manufacturers to submit an offer that complies with the suggested mechanisms for each population. However, as noted in Section 1.8.b.iv of the SFO, additional mechanisms may also be suggested. The State is willing to consider any mechanism that does not create additional delays in seeking approvals from regulatory bodies or other entities and which meets the two stated aims

of the SFO: unlimited access to DAAs for both Medicaid and incarcerated populations at or below the Total 2018 State Spend for those populations.

7. In the description of the Medicaid pricing model, the cost of remaining Medicaid-related DAA purchases that is in excess of the total subscription payment is noted as “\$0.01.” Is there a reason this amount is specified, as compared to zero cost?

The State placed the nominal cost for DAA purchases in excess of the total subscription payment at \$0.01 to maintain consistency across populations served by the model.

However, in the interests of clarification, the SRA would cap the State’s annual Medicaid expenditure for DAAs at or below the State Fiscal Year 2018 Medicaid expenditure for DAAs. For units dispensed after that cap has been reached, the effective expenditure for the State would be \$0. However, Medicaid pharmacy reimbursement would still occur as usual and customary, consistent with State law, the Louisiana Medicaid State Plan, and the MMCO contracts with the State.

8. Will the HCV drug benefit be carved out of Managed Care? If not, is the State still on target to implement a universal PDL prior to July 1st?

No, the DAA drug benefit will not be carved out of Medicaid managed care. On May 1, 2019, the State plans to implement a single preferred drug list applicable to both fee-for-service recipients and MMCO enrollees. DAAs under the SRA will be preferred agents on the single preferred drug list.

9. If the HCV class is not carved out, what role will the Medicaid Managed Care Organizations (“MMCOs”) have in implementing this model?

For MMCO enrollees, MMCOs will be responsible for reimbursing pharmacies for DAAs, including drug ingredient costs and associated fees, in the usual and customary manner as specified in State law, the Louisiana Medicaid State Plan, and MMCO contracts with the State. MMCOs will also reimburse for routine, medically necessary HCV-related care, such as office visits and laboratory tests.

- a) How will the MMCOs be reimbursed?

MMCOs will be reimbursed for HCV-related care through rates established by the State’s actuaries.

- b) Will the MMCOs have a role in determining the winning offer?

No.

10. What will be the formulary coverage of DAAs made by manufacturers that are not offered an award?

State Medicaid programs participating in the Medicaid Drug Rebate Program are required to make payable all drugs for which the manufacturer has signed a rebate agreement with CMS.

Therefore, DAAs from manufacturers not offered an award must be payable; however, they will be non-preferred and subject to utilization controls, which include prior authorization with specified clinical criteria.

11. Can the manufacturer's offer include multiple DAAs to provide coverage to the greatest number of patients possible?

The possibility of implementing a subscription model that utilizes more than one DAA is specifically left open in the SFO. However, offers will be evaluated, in part, based on the genotypes covered by the DAA(s) and on the ability of the offer to minimize the clinical and administrative burden associated with implementing that offer.

12. Is Louisiana willing to amend its supplemental rebate agreement with a manufacturer to allow an offset to rebates owed by the manufacturer to account for payments made to the manufacturer under this model?

The Department is willing to entertain an offer that would involve amending its supplemental rebate agreement to maintain total spending for selected Hepatitis C medications below the maximum annual contract value mentioned in the SFO (Total 2018 State Spend in the Medicaid and Corrections populations).

13. If the 340B program is utilized for DOC, do you anticipate any additional facilities/pharmacies besides LSU Lallie Kemp Regional Medical Center will participate? If only LSU Lallie Kemp Regional Medical Center is used, what treatment model (e.g., Project ECHO) will be used to enable patients to access HCV care (through 340B) throughout the DOC system? Do each of the DOC facilities have dispensing capabilities?

The State has not made any final decisions regarding implementation of the subscription model within the DOC, pending the receipt of offers, including the treatment model to be employed. Yes, every DOC facility has the capability to dispense medications including DAAs.

14. What, if any, approvals from CMS or HRSA will be required?

The State cannot definitively answer this question until all offers have been evaluated. However, the State has sought guidance from CMS and HRSA regarding the mechanisms suggested in the SFO and has taken steps to seek the regulatory approvals required to implement those mechanisms.

15. Do you anticipate that a successful offer could be based on a pricing model that could require CMS approval of a waiver or any other federal approvals?

As noted in the SFO, the State requires all responding manufacturers to submit an offer that complies with the suggested mechanisms for each population. These mechanisms do not require a waiver from CMS. While the State is willing to consider other mechanisms, including those requiring a waiver from CMS, additional delays associated with seeking such approvals from CMS or other regulatory bodies will be factored into the selection process.

16. Would you consider a proposed model that would require an amendment to the Medicaid State Plan?

Yes.

17. With regard to the complementary services, what, if any, discussions have been had with the Office of Inspector General regarding such services?

No such discussions have occurred to our knowledge.

18. Can you provide some examples of “additional mechanisms” that you are interested in evaluating as described in the Evaluation Components in Section 1.9.1 of the SFO?

The SFO is the best evidence of its contents. “Additional mechanisms” in Section 1.9.1 refers to “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.”

19. Under what circumstances would the State exercise its right to make awards to more than one manufacturer? How will the spending cap be allocated in this situation?

The State desires to select the offer representing the simplest, broadest, most comprehensive hepatitis C elimination effort. If one manufacturer chooses to partner with another, as noted in Section 1.18 of the SFO, one manufacturer shall designate itself as the prime contractor and will be responsible for executing any subcontracts necessary to perform its obligations under the subscription model.

20. Are manufacturers that are intending to use subcontractors required to submit parallel information on subcontractors? For example, is it optional or required that manufacturers submit such information under ‘relevant corporate experience’, including customer references, details listed on page 14 of the SFO under ‘administrative data’, and the requested financial statements, for subcontractors?

It is required unless there is some information under the relevant corporate experience section that is inapplicable to the subcontracting arrangement. If that is the case, the offer should so state.

21. Under the subscription model, would DAA prescribing be opened to any licensed physician, including infectious diseases, primary care, addiction medicine, ob/gyn, etc.?

Possibly, as one of the State’s goals in implementing the subscription model is expanding provider capacity and access.

22. What state-sponsored programs are anticipated to educate primary care practitioners regarding screening, linkage to care and treatment of HCV+ patients?

The State is still developing its provider education programs and is open to suggestions or solutions to assist with that effort.

23. What is Louisiana’s plan for screening those who are at high risk for HCV infection such as people who inject drugs and what kind of support is the manufacturer expected to provide for identification/screening and linkage to care for these patients?

The State anticipates developing its own population level screening protocol; however, the State also anticipates that offers of support from the successful manufacturer will assist the State in creating a protocol that enables screening efforts to reach the highest number of people.

24. What weight will you place on the availability of real-world data (e.g., claims, clinical data), with respect to a manufacturer’s DAAs in patients like those who are infected with HCV in Louisiana, in addition to prospective clinical trial data?

The State will place some weight on each element of a prospective offer, including those that relate to real time clinical and claims data in similar populations.

25. Are there particular Health Economics Outcomes Research (HEOR) data specific to a DAA regimen that you would like to have included in the response?

There are no specific requests for such information but the State is open to the inclusion of any data sources that will be of assistance in evaluating the offers and their implications for implementing the subscription model.

26. Is Louisiana planning to monitor and/or publish any data on the overall budget impact of HCV therapy, outside of drug cost? Are systems in place to evaluate anticipated reductions in liver-related mortality, cirrhosis, decompensated liver disease, hepatocellular carcinoma, and liver transplant as a result of broad-based access to DAAs?

The State will monitor the overall budget impact of HCV therapy and reserves the right to publish data regarding such impact at its discretion.

27. For the most recent full year data, what number of chronically infected individuals with hepatitis C were treated within the Medicaid population? What number of chronically infected individuals with hepatitis C were treated within the Department of Safety and Corrections (“Corrections”) population?

Louisiana Medicaid treated about 1,141 unduplicated recipients in calendar year 2018. The clinical criteria for DAA agents were revised in May 2018, allowing more recipients to be treated.

Within the Department of Corrections, about 90 incarcerated individuals were treated for hepatitis C across all facilities.

- For the Medicaid population and Corrections population, respectively, what is the breakdown of number of patients treated by genotype?

The State does not maintain or does not have ready access to this data for either population.

28. Section 1.1.2 of the SFO states that about 39,000 people in Louisiana's Medicaid Program and the Corrections population are known to be chronically infected with hepatitis C. Of these 39,000 people, how many are covered by Louisiana's Medicaid Program? How many are found within the Corrections population?

See Question 1: The State does not know the precise number of current Medicaid beneficiaries or incarcerated individuals who have chronic hepatitis C. Publicly available prevalence estimates for these populations are known to be imprecise and fail to account for higher incidence of disease within vulnerable populations. The State is currently evaluating its existing hepatitis C prevalence data, and the systems from which such data is obtained, in order to more fully develop an accurate and precise count of individuals with hepatitis C in these populations. Population level screening for hepatitis C is not occurring in either Medicaid or Corrections which further limits the State's ability to provide an accurate count. Subject to the preceding caveats, the State's best estimate of the number of current Medicaid enrollees with chronic hepatitis C is roughly 34,000. In addition, and subject to the same caveats, the State's best estimate of the number of individuals currently incarcerated at DOC facilities who have chronic hepatitis C is roughly 5,000.

29. Section 1.8 of the SFO states that responses shall include detailed information regarding the manufacturer's infrastructure and capacity around manufacturing, distributing, supplying, shipping and otherwise making available an adequate supply of direct-acting antivirals to treat at least 10,000 Medicaid and/or incarcerated individuals per year.

- What proportion of these patients are covered by Louisiana Medicaid? What proportion of these patients fall under Corrections?

The proportion of Medicaid and incarcerated patients to be treated before the end of 2020 is unknown and will likely vary over each year of the model.

- Does Louisiana expect to treat 10,000 individuals chronically infected with hepatitis C every year for the duration of the contract? If not, what are the expected treatment rates for each year of the contract?

The first subscription model elimination goal is to treat 10,000 individuals by the end of 2020. Our secondary goal is functional elimination of hepatitis by 2024. The World Health Organization defines elimination as the achievement of measurable global targets set in relation to a specific disease. When reached, continued actions are required to maintain the targets and/or to advance the interruption of transmission.

30. Section 1.1 of the SFO states that the annual contract value should not exceed the FY18 total state spend on hepatitis C medications in the Medicaid population, estimated to be \$30 million, and the FY18 total state spend on hepatitis C medications in the Corrections population, estimated to be \$5 million.

- If expected annual treatment rates as described in the SFO are not achieved, to what extent will respective total state spend amounts for the Medicaid and Corrections populations be adjusted for the next calendar year(s) to achieve elimination goals over the duration of contract(s)?

The Department does not intend to adjust the Annual Contract Value on a yearly basis throughout the award's lifecycle.

31. Section 1.8 of the SFO states that LSU Lallie Kemp Regional Medical Center, a 340B covered entity providing clinical services to inmates on behalf of the Department of Corrections, could purchase DAAs for the Corrections population at a Medicaid Best Price Policy-exempt negotiated price. Are all Louisiana inmates infected with hepatitis C currently treated at LSU Lallie Kemp Regional Medical Center? If not, at what other facilities are inmates being treated for hepatitis C?

DOC inmates with hepatitis C are not treated at Lallie Kemp Regional Medical Center unless there are complications associated with such infection that require out-of-facility treatment. DAA treatment within the DOC currently takes place at the facility level, at more than one facility.

32. What existing capabilities and efforts has the Louisiana Department of Health deployed to date to address the six components of the State's broader Hepatitis C Elimination Program as outlined in Section 1.8 of the SFO?

- **In early 2017, the Office of Public Health's STD/HIV Program ("SHP") applied to the Centers for Disease Control and Prevention and was awarded a Determination of Need for Syringe Service Programs ("SSPs"), based on increasing rates of acute HCV transmission thought to be due to increased injection drug use. In Spring 2017, the State Legislature passed a law that allows the operation of SSPs with local jurisdictional authority approval. Since then, the three largest cities in the State have authorized the creation of SSPs.**
- **The Office of Public Health has developed a directory of major medical facilities and providers currently treating HCV, available at www.louisianahealthhub.org. The website also serves as a central online location for Hepatitis education, screening and treatment locations, and a directory of community partners.**
- **The Office of Public Health, in partnership with the local AIDS Education and Training Center, jointly sponsored two HCV conferences in New Orleans (June 2018) and Shreveport (September 2018) to train medical providers.**
- **The Office of Public Health has leveraged an existing HIV PrEP provider detailer to include HCV and expand from half time to full time effort.**

- **The Office of Public Health has expanded its HIV Linkage to Care Coordinators to now provide services to persons diagnosed with Hepatitis C, but who have not linked to HCV treatment.**
- **Since July 1, 2018, the Office of Public Health has integrated HCV screening and linkage to care at community-based providers already funded for HIV/STI testing with high risk populations, including gay/bisexual men, transgender individuals, and people who inject drugs.**
- **The Office of Public Health is conducting an opioid vulnerability needs assessment of people who inject drugs (PWID) inclusive of a landscape analysis, as well as focus groups comprised of PWID, resulting in concrete recommendations on how to best reach, engage, and deliver services to this population.**
- **SHP is a HRSA SPNS (Special Project of National Significance) site for HIV/HCV coinfection. SHP and the local AIDS Education Training Center have been training medical providers at three agencies in New Orleans and Baton Rouge to leverage practice transformation efforts. Additionally, SHP has expanded their highly impactful HIV Health Models project that promotes HIV viral suppression to include annual HCV screening, patient education and harm reduction.**
- **The Office of Public Health has been working to improve screening rates for baby boomers in primary care at select agencies in New Orleans and the region north of the city through building out EHR and Clinical Decision Support tools, training providers, and educating patients.**
- **The Office of Public Health has developed an HCV Lecture Series that delivers accredited Continuing Education (CE) webinars to medical providers.**
- **SHP has produced a series of SSP Access Fact sheets for parishes that have high need.**
- **In October 2017, Louisiana Health Access Program (LA HAP or the state's ADAP), expanded HCV pharmacy benefits to Ryan White eligible clients.**
- **In May 2018, the Office of Public Health worked with Medicaid and LDH leadership to modify its Prior Authorization criteria and removed prescriber specialty, drug screen, and fibrosis score for HIV/HCV coinfection.**
- **In December 2018, Louisiana partnered with the National Governor's Association to convene officials from payers, manufacturers, and 11 states to share potential strategies to address public health crises by improving access to evidence-based pharmaceutical interventions.**

- **The Office of Public Health recently entered into a Medicaid Data Sharing Agreement that will provide claims and clinical data from both treatment and pharmacy records for Medicaid beneficiaries with hepatitis C.**
- **The current HCV Surveillance Registry is being transitioned from the Office of Public Health’s Infectious Disease Epidemiology Department to the STD/HIV Program, in order to capitalize on the successes that SHP has experienced in developing a nationally recognized HIV surveillance system.**
- **An amendment to the Sanitary Code including all stages of hepatitis C as a reportable condition is in the final stages of approval.**
- **The Office of Public Health recently applied for and received a \$100,000 grant from the Association of State & Territorial Health Officials to improve the reliability of the State’s hepatitis C prevalence data.**

33. Section 1.23 of the SFO states that the Department reserves the right to make multiple awards.

- Does this right include the ability to award contracts to multiple manufacturers based on specific hepatitis C genotypes?

The State desires to select the offer representing the simplest, broadest, most comprehensive hepatitis C elimination effort. The State reserves the right to make multiple awards on any reasonable, rational grounds. However, ease of administrative burden and simplicity of the offered solution will be considered in the scoring of offers.

- If so, how does the Louisiana Department of Health envision apportioning patients across multiple DAAs based on specific hepatitis C genotypes?

The possibility of implementing a subscription model that utilizes more than one DAA is specifically left open in the SFO. However, offers will be evaluated in part on the genotypes covered by the DAA(s) as well as the ability of the offer to minimize the clinical and administrative burden associated with implementing the model.

34. Is the execution of a contract between the Louisiana Department of Health and manufacturer contingent on receiving approval from CMS? To what extent does Louisiana plan to request a waiver from CMS? If a waiver request is planned, what is Louisiana intending to include in the waiver request, and at what date will this request be submitted?

The execution of a contract, or any relevant agreements, will be contingent on approval from the Centers for Medicare and Medicaid Services (CMS) where applicable. The Department does not have current plans to seek any waivers from CMS.

35. Will any part of the implementation of a contract in the desired construct as defined in the SFO require approval by the state legislature? For example, carving the DAA class out of the Medicaid Managed Care pharmaceutical benefit?

To the best of the Department's knowledge, implementation of this initiative utilizing the mechanisms set forth in the SFO will not require legislative approval.

36. Section 1.8 of the SFO contains a mandatory requirement that manufacturer offers include 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. To what extent has Louisiana sought guidance or opinions from the Office of Inspector General to address federal anti-kickback statute risks? Would Louisiana consider an offer from a manufacturer that does not include complementary services?

The State has not received any outside guidance regarding the risk of federal anti-kickback risks and believes that the mechanisms set forth in the SFO do not constitute kickbacks under any federal or state law.

While the State intentionally drafted the SFO in a manner designed to encourage innovative thinking around this public health elimination program, the capacity and willingness of the manufacturer to assist the State across the other elimination strategies is a key component of the scoring.

37. Supplemental Rebate Agreement:

- a) Are you expecting CMS to approve the supplemental rebate agreement negotiated with a manufacturer before that agreement is executed? If so, what steps have you taken (or will you be taking) to facilitate this approval? Does the timeline set forth in section 1.5 of the SFO allow for CMS approval?

The State is in active discussions with CMS regarding a path to approval of a State Plan Amendment and Supplemental Rebate Agreement within the timeline set forth in section 1.5.

- b) Is there an approved draft template supplemental rebate agreement you expect to be using? If so, when and how will it be available to bidders for review?

A draft template is currently under development by the State. It is not yet available for review.

38. What is the State's plan for allowing access to DAAs not selected for the subscription model when such DAA may be more clinically appropriate?

State Medicaid programs participating in the Medicaid Drug Rebate Program are required to make payable all drugs for which the manufacturer has signed a rebate agreement with CMS. Therefore, DAAs from manufacturers not offered an award must be payable; however, they will be non-preferred and subject to utilization controls, which include prior authorization with specified clinical criteria.

39. Section 1.8.a.i of the SFO makes a reference to Corrections DAA purchases being "adjusted over time." How do you envision implementing this adjustment? Does the State expect this adjustment to be done through an upfront discount or rebate? Has the State given thought to how and to whom an upfront discount and/or rebate might be made available/paid?

In the example in the SFO, Corrections DAA purchases would proceed until the spending cap is hit, at which point the 340B price would be reduced to \$0.01 per unit for the remainder of the year. The State has not made any final decisions regarding implementation of the subscription model within the DOC, pending the receipt of offers, including the treatment model to be employed.

40. What guardrails does the State intend to implement to ensure that there is no diversion of product to patients not covered under the terms of the agreement(s)?

The State is open to discussions and suggestions to bolster drug diversion guardrails within the subscription model. Medicaid has a provider integrity program and patients treated in Corrections are under direct supervision.

41. What is the breakdown of the total dollar amount (exclusive of federal match and manufacturer rebates) Louisiana aims to spend in state funds in each year of the contract in Medicaid for each of the following?

- **DAAs: The State intends to enter an SRA that caps the State's annual Medicaid expenditure for DAAs at or below the State Fiscal Year 2018 Medicaid post-rebate expenditure for DAAs. The state funds amount will vary with the applicable federal matching rate.**
- **Associated supply chain costs and DAA distribution: Supply chain costs include professional dispensing fees and pharmacy provider fees, which are dependent on utilization.**
- **Other costs related to the identification, treatment and elimination of Hepatitis C? Based on the offers, the State will estimate the non-pharmacy costs, such as laboratory tests and physician office visits; however, they are not counted in the State Fiscal Year 2018 Medicaid expenditure for DAAs.**

42. Does the State plan to maintain an operational role for Medicaid Managed Care Organizations as a part of the elimination strategy, or will all HCV treatment be centrally managed by the State under a Fee-For-Service model? If so, what is the State's plan for implementation and expected timing?

DAA treatment will be managed dually by the State and its MMCOs. MMCOs will manage DAA treatment for MMCO enrollees, and the State will manage it for fee-for-service enrollees.

43. The SFO defines Medicaid Population to include individuals "enrolled or eligible to enroll in Louisiana Medicaid Program." Will the selected pricing arrangement cover patients who are *eligible to enroll* but not actually enrolled in Medicaid? What is the State's estimate of the eligible to enroll patients in this population?

Within the SFO, "eligible to enroll in Medicaid" refers to any individual who may not be in Medicaid on or about the go-live date of the subscription model but later becomes Medicaid eligible due to any number of changes in circumstance that occur during the pendency of this model. According to the 2017 Louisiana Health Insurance Survey, statewide there were 110,061 adults eligible for but unenrolled in Medicaid expansion.ⁱ

ⁱ <http://ldh.la.gov/assets/media/2017-Louisiana-Health-Insurance-Survey-Report.pdf>