

Louisiana Department of Health
Request for Information on Subscription Payment Models

SUMMARY: Hepatitis C is a lethal and contagious infection causing a public health crisis in Louisiana. This crisis can be mitigated by providing highly effective antiviral treatment to those who are infected. Unfortunately, at current prices, only a tiny fraction of those who need the treatment can receive it. Louisiana is interested in pursuing innovative payment models which will enable the state to eliminate Hepatitis C as a public health problem. The Louisiana Department of Health seeks public input on the creation of a subscription payment model (as described below) for Hepatitis C treatment that will provide access to the Medicaid, uninsured, and correctional populations in Louisiana.

DATES: To be assured consideration, comments must be received by 11:59pm CST on August 24, 2018.

ADDRESSES: Comments should be submitted through the Louisiana Department of Health website at: ldh.la.gov/hepc

FOR FURTHER INFORMATION CONTACT: Pete Croughan at pete.croughan@la.gov with “HCV RFI” in the subject line.

BACKGROUND: Hepatitis C infection kills more Americans than any other infectious disease,¹ and the number of new Hepatitis C virus infections has nearly tripled in the last five years.² Hepatitis C is the reason that death rates from liver cancer continue to increase while overall cancer death rates are decreasing.³ In Louisiana, at least 73,000 people are currently infected with Hepatitis C, a disproportionate number of whom are from low-income and vulnerable populations.

The introduction and continued development of direct-acting antivirals has revolutionized the treatment of Hepatitis C. Sustained virological response to treatment at rates as high as 99% have been documented in patients treated with these medications. However, the price of these treatments continues to present challenges for states interested in making them available to Medicaid and the correctional facility populations, as well as to the uninsured. The cost of treatment for such populations falls disproportionately on the state government, and the Louisiana Department of Health has determined that at current prices, it would be impossible to

¹ Ly KN *et al.* Rising Mortality Associated with Hepatitis C Virus in the United States, 2003–2013. *Clinical Infectious Diseases*, 2016, 62(10): 1287-88.

² CDC. New Hepatitis C Infections Nearly Tripled over Five Years. May 11, 2017. Accessed at <https://www.cdc.gov/nchstp/newsroom/2017/Hepatitis-Surveillance-Press-Release.html>.

³ Cronin KA *et al.* Annual Report to the Nation on the Status of Cancer, part I: National cancer statistics. *Cancer*, 2018. Accessed at <https://doi.org/10.1002/cncr.31551>.

treat all Hepatitis C patients in the state without making significant cuts to other necessary programs.⁴ As a result, the Louisiana Department of Health has considered a number of innovative payment models that might enable the state to eliminate Hepatitis C (without adversely affecting other essential state services) and therefore address the current public health crisis.

The potential payment models the Department has considered include the subscription payment model, voluntary licensing for generic production, bulk purchasing, nominal pricing, value-based pricing, and the use of 28 U.S. Code § 1498. Of these options, the Louisiana Department of Health is soliciting more information about the mechanics of creating a subscription payment model.

Under the subscription payment model, the state would make a set payment to a drug manufacturer or manufacturers for unlimited access to highly effective antiviral treatment for the individuals in Louisiana who are enrolled in Medicaid and in the correctional system for a set period of time. The payment to the manufacturer would be equal to or less, net of Medicaid rebates, than what the state is currently spending to provide DAAs for the Medicaid and correctional populations. This payment would create an incentive for the state to find and treat as many people enrolled in Medicaid as possible. The same payment would also make treatment available to imprisoned populations and potentially to uninsured individuals as well. For the drug manufacturer, this payment model would guarantee a fixed purchase price for a contracted period of time from a large volume payer, and would enable the drug manufacturer to expand their product reach into populations that otherwise would not have received treatment.

CONTACT INFORMATION: Please provide the name, organization, address, contact number, and email address of the commenter.

REQUEST FOR INFORMATION: Subscription Payment Models

QUESTIONS: Respondents are encouraged to provide complete responses to the questions listed below and identify the specific questions they are responding to in their submission. Please note that a response to every question is not necessary for us to consider the responses. Additionally, respondents may identify and comment on other issues that they believe are important for the Louisiana Department of Health to consider in designing these models.

All commenters are encouraged to answer the following questions. For relevant questions, please specify what might be different for correctional, Medicaid, and uninsured populations.

⁴ Louisiana Budget Allocator. Available at <https://drugpricinglab.org/tools/louisiana-budget-allocator/>.

1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?
2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?
3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?
4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?
5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?
6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?
7. For the managed Medicaid population, should this program be “carved out?”
8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?
9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.
10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?
11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

If the commenter is a pharmaceutical company that manufactures a Hepatitis C treatment, we request attention to these questions in addition to the previous questions:

12. Is your company willing to consider a subscription model as outlined above?
13. Are there alternative cost-neutral or cost-saving models you propose to achieve Louisiana’s goal?

14. What length of time would be appropriate for a subscription model contract for Hepatitis C treatment?
15. What special payment considerations (e.g., use of the 340B program) should be considered to ensure access to curative treatment for each population?
16. In what ways would your company be able to support the public health and clinical infrastructure that will maximize access to curative treatment?
17. Are there any other important considerations relevant to your potential participation in a subscription model?

SPECIAL NOTE TO RESPONDENTS: Whenever possible, respondents are asked to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses.

THIS IS A REQUEST FOR INFORMATION (RFI) ONLY. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, application, or proposal abstract. This RFI does not commit the State to contract for any supplies or services or make a grant award. Further, the State is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the State will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense.

Information obtained as a result of this RFI may be used by the State for program planning on a non-attribution basis. All submissions become State property and will not be returned. The State will accept requests from any interested party to keep the information in its submission confidential, and will agree to confidentiality if appropriate in accordance with state and federal law. In all other cases, the State may publicly post a summary of the comments received.