THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700
Philadelphia, PA 19103-7077
215.575.9050 Phone
215.575.4939 Fax

901 E Street NW, 10th Floor
Washington, DC 20004
202.552.2000 Phone
202.552.2299 Fax
www.pewtrusts.org

August 23, 2018

Submitted electronically via ldh.la.gov/hepc

Louisiana Department of Health
628 N. 4th Street
Baton Rouge, LA 70802

Re: Louisiana Department of Health Request for Information on Subscription Payment Models

Dear Secretary Gee –

The Pew Charitable Trusts (Pew) is pleased to offer comments on the Louisiana Department of Health Request for Information (RFI) on Subscription Payment Models. Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative[1] is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

Pew commends the Louisiana Department of Health for its goal to eradicate Hepatitis C (HCV). In particular, we applaud the efforts to extend curative HCV treatment to incarcerated persons and the uninsured, two populations that historically have faced significant barriers in accessing treatment. In this response, we focus our comments on how Louisiana can access discounted pricing for HCV Direct-Acting Antiviral (DAA) therapies for these populations, regardless of whether the discounted pricing is achieved through a subscription model or another approach. We also consider how Louisiana can leverage HCV DAA negotiations to reduce HIV treatment costs for incarcerated populations and how Louisiana can simultaneously build a framework to reduce overall drug costs in the correctional system. These comments do not address potential sources of funding to cover the costs care associated with diagnosing and treating HCV and other conditions.

* * *

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?

Pew commends Louisiana for including correctional and uninsured populations in its elimination strategy, as these two populations are generally unable to access the discounted drug prices available

[1] The Pew Charitable Trusts. "Drug Spending Research Initiative," http://www.pewtrusts.org/en/projects/drug-spending-research-initiative.

under the Medicaid program. Pew has published an analysis, including model administrative or legislative text, detailing how states can access discounted drug prices for correctional populations through discounted manufacturer sales to a designated 340B-eligible provider, such as an academic hospital affiliated with a public medical school or a network of community health centers; this policy could also be used to allow uninsured patients to access HCV DAA treatments at discounted prices.

The Medicaid Drug Rebate Program (MDRP) Best Price requirement has been cited as a barrier to extending discounted drug pricing to incarcerated and uninsured populations.[2] Under the Medicaid statute, the lowest price a drug manufacturer offers to certain purchasers on any product must also be made available to all Medicaid programs. In addition, the manufacturer is required to make that discounted price available to all entities participating in the 340B Drug Discount Program, a federal program which provides discounts to hospitals and clinics that meet federal standards for serving low-income or uninsured patients.[3] If a manufacturer were to sell deeply discounted HCV DAA treatments directly to a state department of corrections, an individual correctional facility or a clinic for uninsured patients, that could trigger the best price requirement, discouraging the manufacturer from offering these discounts.

The Medicaid best price provision of the law has a variety of carveouts that allow manufacturers to offer discounts to certain providers without establishing a lower Medicaid price. One of these carveouts exempts all discounts given to 340B covered entities, regardless of whether the discount is required under the 340B program or whether the discount is voluntary.[4] This is an important distinction – while patients must meet certain requirements to be entitled to the mandatory 340B discount, they do not need to meet these requirements to receive a voluntary manufacturer discount via a 340B entity.

Manufacturers may voluntarily provide discounts to these hospitals outside of the 340B program without triggering best price and without requiring incarcerated adults to be transported to the hospital.[5] If manufacturers provided a voluntary discount to a designated 340B academic hospital or hospitals for incarcerated adults, correctional facilities would not have to transport incarcerated adults to the 340B hospital to receive discounts, a logistically challenging and costly process. Instead, correctional facilities could use telemedicine or have physicians from the 340B hospital visit the correctional facility for diagnosis; prescriptions would be mailed or couriered from the 340B hospital's pharmacy and the correctional facility or department would reimburse the 340B hospital. Because voluntary discounts to 340B hospitals are exempted from best price regardless of whether the patient

---

[2] Ted Alcorn, "Hepatitis C Drugs Save Lives, but Sick Prisoners Aren't Getting Them," The New York Times, March 15, 2018, https://www.nytimes.com/2018/03/15/us/hepatitis-c-drugs-prisons.html. According to the article, "Like other drugmakers, Gilead promises its best price to state Medicaid programs, the Department of Veterans Affairs, and certain hospitals. If the company lowered the price for prisons, Mr. Alton said, it would have to further reduce it for these other entities. Giving prison health systems access to the same discounted price would require an act of Congress."

[3] 42 U.S.C. § 1396r-8(c)(1)(C).

[4] 42 C.F.R. § 447.505(c)(2). For a discussion of this policy, see 81 Fed. Reg. 5170, 5256-7.

[5] Centers for Medicare & Medicaid Services, "Covered Outpatient Drug Final Rule With Comment (CMS-2345-FC): Frequently Asked Questions" (July 6, 2016), https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf.

meets 340B eligibility criteria, manufacturers would not face any best price liability under this arrangement.

This model would also allow uninsured patients to access discounted HCV DAA pricing without having to meet the 340B patient eligibility criteria. Uninsured patients could be seen at the designated 340B hospital for HCV diagnosis and treatment, or could be treated by another local health care provider, such as at a community health center, in consultation with providers at the 340B hospital; the uninsured patient's medication would be distributed from the stock of discounted HCV DAA treatments maintained by the 340B hospital under the program.

How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C? How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?

Both academic hospitals affiliated with public medical schools and community health center networks may be candidates to manage the treatment of HCV and distribution of HCV DAAs under a statewide discounted drug acquisition program. These entities have clinical experience in HCV treatment, and in most cases they qualify for and participate in the 340B program. While Pew has not analyzed the specific organizational and clinical capacity of these providers in Louisiana, we provide general comments on how either provider could administer such a program. In addition, in 2016 the Louisiana Department of Public Safety and Corrections reported to Pew researchers that it had contracted with a 340B provider to provide specialty care for some incarcerated persons, which allowed the department to access discounts for prescriptions related to that care.[6] The voluntary discount model discussed here is distinct from that approach.

Under an academic medical center model, the discounted HCV DAA distribution structure could resemble a hub-and-spoke system, with a centralized process for determining patient eligibility and drug delivery. In this model, the state would negotiate a discounted price on the medication with the manufacturer. The manufacturer would sell drugs to the 340B-eligible academic medical center at the negotiated price, and the academic medical center would maintain the drugs in a separate inventory. 340B-eligible hospitals generally already maintain separate inventories for drugs purchased under the 340B program and non-340B purchases, as not all patients are eligible to receive 340B-purchased drugs.[7] The academic medical center would leverage its existing inventory model to incorporate purchases under the discounted HCV DAA program. When a patient is determined to be eligible for the program under the state's criteria, the academic medical center would enroll the patient in the program and provide a variety of clinical and adherence management services, including distribution of the HCV DAA to the patient from its central pharmacy; clinical services could be provided either in-person or through telemedicine, which could facilitate treatment of incarcerated persons. The state would make a

---

[6] The Pew Charitable Trusts, "Pharmaceuticals in State Prisons" (December 2017), http://www.pewtrusts.org/~/media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf.

[7] Wright, S. "Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431," Department of Health and Human Services Office of Inspector General (Feb. 4, 2014). https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. (discussing various 340B inventory management systems).

capitated payment to the academic medical center for the entire care package provided, acting entirely as an insurer and not a purchaser of the HCV DAA.

Under a community health center (CHC) network model, a statewide CHC network would have a contract with the state to administer the program. The CHC would leverage its existing 340B inventory management framework to segregate discounted HCV DAAs purchased under this program from other inventory, distributing them only to eligible patients. If patients eligible for the discounted HCV DAA program, as defined by the state, are widely distributed across the state in areas served by the CHC network, this model may present administrative efficiencies compared to a hub-and-spoke centralized model. CHCs could see eligible patients directly, linking them to any other needed health or social services. As in the academic medical center model, the state would make a capitated payment to the CHC for the entire care package provided, acting entirely as an insurer and not a purchaser of the HCV DAA.

Because this discount model relies on the 340B eligibility of the purchasing agent, whether an academic medical center or a CHC, to avoid triggering best price, it is essential that any reimbursement for the discounted HCV DAA from the state must not be considered a best price-eligible transaction. If community pharmacies are involved in distributing discounted HCV DAAs, the state must ensure that these transactions be exempt from best price; registering designated community pharmacies as contract pharmacies[8] of the 340B entity selected to manage the discounted HCV DAA purchasing would facilitate community pharmacy participation in the program, as drugs distributed by these community pharmacies would still be considered under the auspices of the selected 340B entity and therefore would not trigger the best price provision.

For the managed Medicaid population, should this program be "carved out?"

When a drug is "carved out" from the managed Medicaid population, meaning that coverage for the drug is administered by the state and not a Medicaid Managed Care Organization (MCO), the state may gain additional negotiating ability with a manufacturer by representing a larger number of eligible patients. However, this may diminish MCOs' negotiating power, both for the drug that is carved out as well as other drugs made by the same manufacturer. The market for HCV DAAs contains multiple manufacturers with therapeutically similar products, and MCOs may already prefer one particular HCV DAA in exchange for greater manufacturer discounts on the preferred product, but also on other drugs sold by the manufacturer. Therefore, if HCV DAAs are carved out from managed Medicaid, this could result in higher net costs on other drugs. Louisiana should ask MCOs whether any current non-HCV DAA discounts are contingent on the formulary status of HCV DAAs and what cost increases the MCO anticipates if HCV DAAs are carved out. The state should then consider whether the increased discounts available for carving out HCV DAAs results in greater cost savings overall than allowing MCOs to continue negotiating comprehensive formulary discounts based upon HCV DAA treatment.

[8] Health Resources and Services Administration Office of Pharmacy Affairs. "Contract Pharmacy Services" (May 2018). https://www.hrsa.gov/opa/implementation/contract/index.html.

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.

While Pew cannot provide a legal assessment of a specific program, we note that the method of extending discounts to correctional and uninsured populations described in these comments is consistent with existing federal regulations and statutes and would be unlikely to require any waivers or additional guidance. A manufacturer may inform the Centers for Medicare & Medicaid Services (CMS) through a "reasonable assumptions" letter of the arrangement and the manufacturer's assessment that any sales under this program would not trigger the Medicaid best price provision;[9] this allows CMS an opportunity to respond to the manufacturer's assumptions if CMS does not agree with them.

Is there anything else you would like to share with the Department related to our consideration of a subscription model?

As Louisiana builds the infrastructure to enable correctional facilities to access discounted HCV DAA pricing, it should consider how this infrastructure could be leveraged to ensure correctional facilities and uninsured patients are able to access other drugs at discounted prices. Drug spending has an outsized impact on correctional healthcare budgets: of states that report drug spending, the majority spend over 15% of their correctional health care budget on drugs, with some states spending up to 32%.[10] Many incarcerated persons with HCV may also be living with HIV;[11] since many HIV treatments are produced by the same manufacturers as HCV DAAs, Louisiana may consider simultaneously negotiating discounts for HCV DAAs and HIV treatments for incarcerated populations. In selecting an academic medical center or CHC to administer the discounted HCV DAA program for the correctional population, Louisiana should consider the entity's ability to administer a larger discounted drug program for the correctional population, such as the proposal to extend Medicaid discounts to correctional populations as a condition for a manufacturer's inclusion on the Medicaid Preferred Drug List.

* * *

[9] Department of Health and Human Services Office of Inspector General. "Reasonable Assumptions in Manufacturer AMP Reporting" (2017). https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000216.asp. *See also* 42 CFR § 447.510(f)(1)(i) (Requirements for manufacturers, "The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations.").

[10] The Pew Charitable Trusts, "Pharmaceuticals in State Prisons" (December 2017), http://www.pewtrusts.org/~/media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf.

[11] Hennessey KA et al. Prevalence of infection with hepatitis B and C viruses and coinfection with HIV in three jails: a case for viral hepatitis prevention in jails in the United States, in Journal of Urban Health, Vol. 86, pp. 93–105, 2008.

We appreciate the opportunity to respond to this RFI and commend the state for its attention to the Hepatitis C public health crisis in Louisiana. Should you have any further questions, please contact me at ireynolds@pewtrusts.org.

Sincerely,

Ian Reynolds
Manager, Drug Spending Research Initiative
The Pew Charitable Trusts
202.540.6512