

## CASE AND COMMENTARY

### How Should Physicians Steward Limited Resources While Ensuring That Patients Can Access Needed Medicines?

Pete Croughan and Rebekah E. Gee, MD, MPH

#### Abstract

Hepatitis C poses public health and fiscal crises for state Medicaid programs trying to respond to this epidemic. Meager funding streams, a lack of negotiating power, and escalating pharmaceutical prices exacerbate the financial strain placed on these programs as they struggle to meet public health priorities. The Louisiana Department of Health has adopted a subscription model for hepatitis C treatment, but costly medications continue to challenge states' capacities to cover patients who need costly drugs.

#### Case

Dr X serves as chief medical officer for the state Department of Health and sees patients at a local federally qualified health center. Recently, an exciting, expensive new drug was released, which cures all strains of hepatitis C. The state Department of Health approaches Dr X to help draw up Medicaid access guidelines for this new drug, citing that the state cannot afford to cover this drug for all patients with hepatitis C. The Secretary of the Department of Health asks Dr X to define clinical criteria, such as liver fibrosis stage or substance use status, to help prioritize which patients should have access to the drug under Medicaid. Dr X understands the reality of the state's financial restrictions and agrees to offer a prioritized list of clinical criteria.

Later that week, upon examining the health record of a patient, Mr R, Dr X notices that Mr R has a prior hepatitis C diagnosis. A note in the record suggests that Mr R wasn't approved by Medicaid to receive therapy for hepatitis C because of his continued substance abuse. Mr R has gone through multiple substance abuse treatments in the past and has relapsed back into self-abusive behaviors soon after each treatment. Dr X also notices that Mr R is jaundiced, however, and remains concerned that Mr R has advanced liver damage. Dr X sends Mr R for liver function testing, fearing that Mr R will not qualify for a liver transplant if his test results show poor function. If that's the case, a pharmaceutical agent might be Mr R's best hope for treatment.

Dr X wonders how to balance the need for population-level guidelines about access against interests of individual patients like Mr R.

## Commentary

This case demonstrates a tension between fiscal and clinical needs regarding costly prescription drugs for hepatitis C. To help think through this case, we consider how this kind of tension has been managed in Louisiana.

In 2013, hepatitis C killed more Americans than 60 other infectious diseases combined,<sup>1</sup> and it represents a public health and fiscal crisis. The opioid epidemic has furthered the spread of the hepatitis C virus.<sup>2</sup> According to the Louisiana Office of Public Health, an estimated 89 000 Louisianans are infected with it.<sup>3</sup> A large proportion of these individuals have medical expenditures paid by the state, either through Medicaid or the Department of Corrections. However, the high costs of drugs that eliminate this virus—even accounting for federal and supplemental rebates—prohibit the state from providing them to larger numbers of patients. In 2017, Louisiana treated less than 3% of known hepatitis C infections among patients covered by Medicaid.<sup>4</sup>

Some Medicaid programs are now seeking to leverage substantial [decreases in pharmaceutical costs](#) through new strategies such as closed formularies and spending growth caps.<sup>5</sup> Although the [Medicaid Drug Rebate Program](#) confers a notable benefit of guaranteeing Medicaid programs' access to the best price in the market, it also requires state programs to cover almost every medication of manufacturers who sign a national rebate agreement with the Secretary of the US Department of Health and Human Services.<sup>5</sup> According to the Medicaid and Children's Health Insurance Program Payment and Access Commission, total Medicaid spending on outpatient drugs increased 38.2% from 2013 to 2015, largely attributable to the introduction of branded formulations of sofosbuvir, ledipasvir/sofosbuvir, and ombitasvir/paritaprevir/ritonavir and dasabuvir.<sup>6</sup> Meanwhile, most states are required by law to balance their budget each year,<sup>7</sup> creating a zero-sum predicament: If one area of the budget increases unexpectedly, another area must be cut to compensate. Where should cuts be made?

### Competing Challenges for Sparse Funds

According to the 2018 America's Health Rankings, Louisiana is the least healthy state in the nation.<sup>8</sup> The hepatitis C crisis is one of many infectious disease crises in Louisiana. Two of 5 US cities with the highest rates of HIV are New Orleans and Baton Rouge (ranked fourth and fifth, respectively, in 2017).<sup>9</sup> Nationwide, in 2017 Louisiana ranked third in AIDS case rates and third in case rates of primary and secondary syphilis.<sup>9</sup> In addition to having high rates of infectious diseases, Louisiana is among the states with the highest rates of maternal mortality,<sup>10</sup> diabetes, and smoking.<sup>11</sup> When looking for root causes of these health outcomes, one finds that Louisiana has the highest average percentage of people living in poverty in any state,<sup>12</sup> has weathered the largest cuts to state funding for higher education on a per-pupil basis since 2008,<sup>13</sup> and has had the highest homicide rate in the United States for 29 years in a row.<sup>14</sup>

Despite these unmet needs, meager funding streams could still be cut. In budget negotiations for 2018, the Louisiana Department of Health was threatened with more than \$500 million in state general fund reductions. With no solution only weeks prior to the end of the fiscal year, the Department of Health was forced to notify 37 000 seniors and persons with disabilities in nursing homes that their Medicaid eligibility and, in turn, their housing was at risk of being eliminated.<sup>15</sup> Meanwhile, a major academic and safety net hospital in the heart of Cajun country, Lafayette General Health, notified 800 employees that their employment would be terminated if the state was unable to resolve the budget crisis.<sup>16</sup> Fortunately, an agreement was reached, but such notices demonstrate just how tenuous the Medicaid safety net is.

### **The Subscription Model**

Given perennially jeopardized funding streams, the Louisiana Department of Health sought an alternative mechanism to dramatically expand access to treatment for large numbers of persons with hepatitis C without undermining capacity to respond to other critical needs. One alternative mechanism being pursued is the subscription payment model, according to which the state pays drug manufacturers for unlimited access to medications for a specified time period for patients enrolled in Medicaid or in Louisiana's [correctional system](#).<sup>17</sup> This model has also been described as "Netflix style," reflecting the application of subscription-based pricing in the pharmaceutical sector.<sup>18</sup> Payment to a drug manufacturer would be equal to or less than what the state is currently spending to provide antiviral drugs to these populations. Patients with hepatitis C would receive the unrestricted treatment access they deserve, and the drug manufacturer partnered with the state would receive a stable revenue stream and larger market share. A similar model in Australia showed that providing unrestricted access to antivirals for hepatitis C at a cost of US\$766 million over 5 years produced estimated savings of US\$4.9 billion to the Australian government compared to conventional per-unit pricing.<sup>19</sup> Applying the subscription model at the state level in the United States would allow policymakers to pursue hepatitis C elimination without jeopardizing other public health priorities. For clinicians like Dr X, removing the financial barrier to treatment would allow him to make recommendations based solely on his clinical judgment and what's best for patients like Mr R.

### **Conclusion**

States' adoption of the subscription model affords a possible solution to the hepatitis C epidemic. However, in the absence of regulatory or market pressure to broadly reduce the price of pharmaceuticals, state policymakers will continue to struggle to meet the needs of patients requiring high-cost drugs; each new high-cost breakthrough will pit one disease against another and one meaningful public health program against another.

## References

1. Ly KN, Hughes EM, Jiles RB, Holmberg SD. Rising mortality associated with hepatitis C virus in the United States, 2003-2013. *Clin Infect Dis*. 2016;62(10):1287-1288.
2. Increase in hepatitis C infections linked to worsening opioid crisis [press release]. Atlanta, GA: Centers for Disease Control and Prevention; December 21, 2017. <https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection.html>. Accessed February 13, 2019.
3. Louisiana Office of Public Health. Epidemiological profile of hepatitis C infection in Louisiana—2015. <http://ldh.la.gov/assets/oph/Center-PHCH/Center-CH/infectious-epi/Hepatitis/HepCEpiProfile2016.pdf>. Published 2016. Accessed May 7, 2019.
4. Louisiana Department of Health. Solicitation for offers: pharmaceutical manufacturer(s) to enter into contract negotiations to implement hepatitis C subscription model. [http://ldh.la.gov/assets/oph/SFO/LDH\\_Hep\\_C\\_SFO.pdf](http://ldh.la.gov/assets/oph/SFO/LDH_Hep_C_SFO.pdf). Published January 10, 2019. Accessed May 15, 2019.
5. Young K, Garfield R. Snapshots of recent state initiatives in Medicaid prescription drug cost control. *Henry J. Kaiser Family Foundation Issue Brief*. February 21, 2018. <https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/>. Accessed May 15, 2019.
6. Medicaid and CHIP Payment and Access Commission. High-cost hepatitis C drugs in Medicaid: final report. <https://www.macpac.gov/publication/high-cost-hcv-drugs-in-medicaid/>. Published March 2017. Accessed December 3, 2018.
7. Rudowitz R, Orgera K, Hinton E. Medicaid financing: the basics. *Henry J. Kaiser Family Foundation Issue Brief*. March 21, 2019. <https://www.kff.org/report-section/medicaid-financing-the-basics-issue-brief/>. Accessed May 15, 2019.
8. America's Health Rankings website. <https://www.americashealthrankings.org/>. Accessed December 12, 2018.
9. Louisiana Department of Health. Louisiana HIV, AIDS, and early syphilis surveillance: quarterly report. 2018;16(4). [http://ldh.la.gov/assets/oph/HIVSTD/HIV\\_Syphilis\\_Quarterly\\_Reports/2018Reports/Fourth\\_Quarter\\_2018\\_HIV\\_Syphilis\\_Report.pdf](http://ldh.la.gov/assets/oph/HIVSTD/HIV_Syphilis_Quarterly_Reports/2018Reports/Fourth_Quarter_2018_HIV_Syphilis_Report.pdf). Accessed February 10, 2019.
10. Kiltyka L, Mehta P, Schoellmann K, Lake C; Louisiana Department of Health. Louisiana maternal mortality review report, 2011-2016. [http://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/maternal/2011-2016\\_MMR\\_Report\\_FINAL.pdf](http://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/maternal/2011-2016_MMR_Report_FINAL.pdf). Published August 2018. Accessed December 12, 2018.

11. Centers for Disease Control and Prevention. BRFSS prevalence & trends data. <https://www.cdc.gov/brfss/brfssprevalence/>. Updated September 13, 2017. Accessed February 13, 2019.
12. US Census Bureau. Current population survey, 2015 to 2018 annual social and economic supplements. Percentage of people in poverty by state using 2- and 3-year averages: 2014-2015 and 2016-2017. <https://www2.census.gov/programs-surveys/demo/tables/p60/263/statepov.xls>. Accessed February 10, 2019.
13. Louisiana's cuts to higher education are shortchanging future generations [press release]. Baton Rouge, LA: Louisiana Budget Project; October 4, 2018. <https://www.labudget.org/2018/10/release-louisianas-cuts-to-higher-education-are-shortchanging-future-generations/>. Accessed February 13, 2019.
14. Is New Orleans to blame for Louisiana's nation-leading murder rate? Data says no. *New Orleans Advocate*. September 25, 2018. [https://www.theadvocate.com/new\\_orleans/news/crime\\_police/article\\_e9dd6d1c-c077-11e8-9728-1f7f22bc4569.html](https://www.theadvocate.com/new_orleans/news/crime_police/article_e9dd6d1c-c077-11e8-9728-1f7f22bc4569.html). Accessed May 7, 2019.
15. Begnaud D. Thousands of elderly, disabled face eviction from Louisiana nursing homes over Medicaid cuts. *CBS News*. May 9, 2018. <https://www.cbsnews.com/news/thousands-of-elderly-disabled-face-eviction-from-louisiana-nursing-homes-over-medicaid-cuts/>. Accessed February 13, 2019.
16. Guidry L. Lafayette General issues "layoff" letters to 800 employees, starts "Save UHC" movement. *Daily Advertiser*. April 30, 2018. <https://www.theadvertiser.com/story/news/2018/04/30/lafayette-general-issues-warn-letters-800-employees-starts-save-uhc-movement/555283002/>. Updated May 1, 2018. Accessed February 13, 2019.
17. Louisiana Department of Health. Department of Health issues request to choose partner for hepatitis C drug payment model. <http://ldh.la.gov/index.cfm/newsroom/detail/5020>. Published January 10, 2019. Accessed February 10, 2019.
18. Trusheim MR, Cassidy WM, Bach PB. Alternative state-level financing for hepatitis C treatment—the "Netflix model." *JAMA*. 2018;320(19):1977–1978.
19. Moon S, Erickson E. Universal medicine access through lump-sum remuneration Australia's approach to hepatitis C. *N Engl J Med*. 2019;380(7):607-610.

**Pete Croughan** is a medical student at the University of California, San Francisco, School of Medicine. He previously served as policy director at the Louisiana Department of Health, where he worked on financing for graduate medical education, pharmaceutical policy, analyzing federal health reform efforts, and developing a statewide cancer

strategy. He then served as chief of staff for the department, where he oversaw policy, communications, legislative affairs, and external affairs.

**Rebekah E. Gee, MD, MPH** is Secretary of the Louisiana Department of Health as well as an associate professor (currently on leave) at the Louisiana State University School of Medicine and School of Public Health in New Orleans. She is an obstetrician-gynecologist and trained policy expert whose oversight responsibilities include public health and other direct service programs for citizens in need including behavioral health services, developmental disabilities services, aging and adult services, emergency preparedness, and the Medicaid program.

#### **Editor's Note**

The case to which this commentary is a response was developed by the editorial staff.

#### **Citation**

*AMA J Ethics.* 2019;21(8):E630-635.

#### **DOI**

10.1001/amajethics.2019.630.

#### **Conflict of Interest Disclosure**

The author(s) had no conflicts of interest to disclose.

*The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.*

**Copyright 2019 American Medical Association. All rights reserved.  
ISSN 2376-6980**