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INNOVATIVE PAYMENT MODELS

AN ANALYSIS OF
THE PROMISE AND PRACTICE
OF NOVEL HEPATITIS C MEDICATION
PROCUREMENT STRATEGIES
IN THE U.S.



AN INNOVATIVE PAYMENT MODEL
IS A TERM USED TO DESCRIBE
VARIOUS NOVEL DRUG
PROCUREMENT STRATEGIES BEING
UTILIZED BY A GROWING NUMBER
OF STATES AS A COST-EFFECTIVE
WAY TO PAY FOR LARGE
QUANTITIES OF DIRECT ACTING
ANTIVIRAL MEDICATION THEY
NEED TO TREAT THE THOUSANDS
OF PEOPLE WITH HCV WHO
RECEIVE STATE-COVERED HEALTH
CARE THROUGH MEDICAID OR
WHILE INCARCERATED IN STATE
CORRECTIONAL FACILITIES.

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INTRODUCTION

HEPATITIS C VIRUS (HCV) IS THE MOST COMMON AND DEADLY BLOOD-BORNE INFECTION IN THE UNITED STATES, with an estimated 2.4 million persons chronically infected.¹ It is also one of the few significant public health threats for which there exists a highly effective, easily administered cure. The advent of direct acting antivirals (DAAs) has made the goal of treatment and cure from HCV an attainable goal in the U.S. The cost of the drugs, along with other impediments to HCV treatment and care, such as lack of reliable screening and linkage to care, and the lack of continuity of care, however, can create a barrier to widespread access to HCV treatment. Market competition has led the net cost of DAAs to fall over time, yet cost concerns remain, leading some payers to impose restrictions to limit the number of DAA prescriptions. Some payers only allow certain specialty physicians to prescribe DAAs, and require those with a history of substance use to provide proof of up to 1 year of sobriety before approving them for DAA treatment.² These barriers are evident in how, despite the availability of DAAs since 2013, the U.S. has managed to cure only 37% of people with HCV.³

Several states, such as Louisiana and Washington, have developed HCV elimination plans to create systemic strategies to increase prevention, testing, and treatment.^{4,5} State health authorities are particularly burdened by the dilemma of stretching extremely limited resources to meet the needs of those receiving state-covered health care. HCV prevalence is disproportionately higher among those covered by Medicaid, and in state correctional facilities, where rates of HCV have been reported as high as 40%, compared to a 1% HCV prevalence in the general population.^{6,7} As part of their HCV elimination plans, Louisiana and Washington became the first states to utilize **innovative payment models** to increase their ability to secure more drugs to meet the treatment needs of those they cover. Through these models—also referred to as **subscription models**—the states enter into an agreement with an HCV treatment manufacturer to pay a set price for access to an unlimited supply of the company’s HCV medication over a period of several years.⁸ These novel payment arrangements can be greatly beneficial tools to increase supply of available treatment dosages, but they are not standalone “silver bullet” solutions to HCV elimination. They must be complemented by robust HCV elimination strategies that address barriers to HCV care, emphasize efforts that identify existing cases, prevent new infections, and provide a pathway to treatment and cure for as many as possible.

This paper analyzes similarities and contrasts in enacted and emerging innovative payment models in three states—Louisiana, Washington, and Michigan. It describes varied applications of these types of models, progress to-date at increasing HCV treatment rates, and assesses how the plans currently being implemented are impacting access to treatment. Finally, the paper provides recommendations on how existing and future models can be adapted to optimize outcomes that will lead to HCV elimination.

INNOVATIVE PAYMENT MODELS

AN INNOVATIVE PAYMENT MODEL (IPM) is a term used to describe various novel drug procurement strategies being utilized by a growing number of states as a cost-effective way to pay for large quantities of DAA medication they need to treat the thousands of people with HCV who receive state-covered health care through Medicaid or while incarcerated in state correctional facilities. Through IPMs, state health authorities negotiate agreements with pharmaceutical companies for a maximum annual expenditure amount for an unlimited supply of a drug.⁹

A core principle to the success of these models is the mutual interest of both contracting parties to maximize distribution of the drugs to as many people as possible. Health authorities can set a predictable expenditure amount within their budgetary means, while achieving the public health objective of providing widespread access to HCV treatment. Manufacturers negotiate a new revenue stream and means of distribution for its product that will widen its market share. Ideally, these interests will incentivize both parties to maximize investment in strategies such as screening and linkage to care to identify and treat as many cases as possible, which is essential to ultimately achieving elimination.

AUSTRALIA'S WIDESPREAD DAA ACCESS MODEL

Australia was one of the first countries to use this type of purchasing model to procure DAAs.¹⁰ In the beginning of 2016, approximately 230,000 Australians had HCV—nearly 1% of the population.¹¹ In correctional facilities, HCV prevalence ranged from 2%-40%.¹⁰ Following an assessment and recommendation by the Pharmaceutical Benefits Advisory Committee, several DAAs were added to the country's national reimbursement list—the Pharmaceutical Benefits Scheme (PBS)—in March 2016, so they would be covered under the national health care system.¹⁰ While the responsibility to provide health care for incarcerated persons generally is that of the state or territory operating the prison, the government agreed to fund the cost to provide HCV treatment in the nation's correctional facilities through the PBS.¹⁰ The country's health authority also removed all restrictions to treatment, making DAAs available to all persons with a confirmed clinical diagnosis, and expanded authority to allow general practitioners as well as specialists to prescribe DAAs.¹⁰ Prior to the listing on the PBS, DAA treatment cost Australians up to AU\$100,000 (\$77,219 USD).¹² Now, the maximum charge to a beneficiary for a full course of DAA treatment is an AU\$41.30 (\$31.89 USD) co-payment.¹³

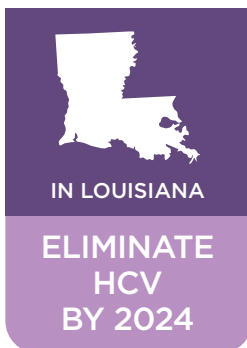
To address cost concerns, the Department of Health entered into Special Pricing Deeds of Agreement with DAA manufacturers to negotiate confidential discounted pricing arrangements for an unlimited supply of the medications.^{14,15} Following the recommendation to add HCV treatment to the PBS, the Australian Government committed more than AU\$1 billion (\$772 million USD) to fund the purchase of the newly covered medications over 5 years.¹²

From the inception of the policy in March 2016 to December 2019, 82,280 Australians initiated DAA treatment, with an increase in lifetime treatment uptake by people with known diagnoses from 11.1% in 2015 to 64.2% in 2019.¹⁰ During the same period, the percentage of treatment initiations in various jurisdictions that occurred in correctional settings ranged from between 10.1% -39.2%. Sustained virologic response (SVR) results taken at least 8 weeks after treatment initiation were reported for 51.5% of those who initiated treatment between 2016 -2019 and showed a 93% overall cure rate.¹⁰

While the exact terms of the payment arrangements made between the Australian government and the pharmaceutical manufacturers are confidential, the PBS reported 2 DAAs—sofosbuvir/velpatasvir (Epclusa), and glecaprevir/pibrentasvir (Mavyret)—as its 6th and 10th most costly drug expenditures from July 2019 to June 2020, with 27,661 total prescriptions filled for both drugs in that period at a cost of over AU\$409 million (\$315 million USD).¹⁶

The government’s committed investment of fiscal and logistical resources to support this effort has set Australia on a course to achieve the WHO HCV elimination goals of 80% treatment coverage and 90% reduction in incidence by 2030.¹⁰ Consistent and adequate resource allocations to increase testing and navigation into treatment, particularly among people who inject drugs, are essential to achieving these goals.

MODIFIED SUBSCRIPTION MODELS



LOUISIANA “EXPENDITURE CAP” MODEL

Based on Australia’s success, it is not surprising that IPMs have gained traction in the U.S. as well. Louisiana was the first state to implement an IPM to acquire HCV medication.

There are 39,000 people living with HCV either enrolled in Louisiana’s Medicaid program or held in its eight state prisons.¹⁷ Historically, cost concerns led Louisiana to impose severe restrictions on providing DAA treatment for HCV to Medicaid recipients and incarcerated persons. Treatment access in state prisons was largely limited to those with advanced liver damage or comorbidities such as HIV or those on dialysis.¹⁸ Medicaid limited treatment to those with advanced liver damage, and required that eligible treatment recipients with a history or substance use provide evidence of a year of sobriety.¹⁹ In 2018, the \$35 million the state spent on HCV drug treatments only covered the cost to treat fewer than 3% of persons with HCV who received state Medicaid benefits or were in state prisons.⁴ The state decided to pursue implementation of a subscription model similar to Australia’s to enable it to control costs and secure a greater amount of DAA to meet treatment needs. The Louisiana Department of Health (LDH) released a solicitation for offers on January 10, 2019 that sought a pharmaceutical company to partner with the state to implement a dual approach strategy to achieve HCV elimination: 1) implementing a subscription model to secure the medication, and 2) providing complimentary services and resources to support the state’s broader elimination program that includes efforts to improve screening, provider capacity, and linkage to care.²⁰

LOUISIANA'S MODIFIED PAYMENT MODEL SET AN ANNUAL MAXIMUM DOLLAR AMOUNT—KNOWN AS AN ANNUAL EXPENDITURE CAP— THAT THE STATE WOULD PAY TOWARDS THE PURCHASE OF DAAs FROM A CONTRACTED MANUFACTURER.

Initially, LDH planned to solicit for a payment option where it would pay a flat fee amount up front for an unlimited amount of DAA treatment.²¹ Medicaid's existing statutory pricing and reimbursement rules, however, are not structured for this type of payment design. Thus, LDH would have been required to obtain a Medicaid waiver from the Centers for Medicare and Medicaid Services (CMS) to enact this unique payment scheme.²² This process may have taken two years to complete, and its novelty lent to uncertainty of its approval. Ultimately, LDH decided to avoid the waiver process by utilizing supplemental rebates the manufacturer issues to the state for Medicaid drug purchases, and 340B discounts to purchase drugs for use in non-Medicaid settings, namely state correctional facilities.¹⁷

Instead of paying an upfront lump-sum, the resulting modified payment model set an annual maximum dollar amount—known as an annual **expenditure cap**—that the state would pay towards the purchase of DAAs from a contracted manufacturer.²³ This amount was equal to the amount the state spent in the previous fiscal year to provide the antiviral medications. Louisiana set this amount to mirror the state's 2018 DAA expenditures for each agency.¹⁷ Under this agreement, Louisiana purchases DAAs for its Medicaid program from the manufacturer at a negotiated price that utilizes only the federal drug rebates. Drugs for use within the state Department of Corrections would be purchased utilizing 340B rebates to discount the cost.¹⁷ The state would purchase drugs at these discounted prices up to an agreed upon contracted annual expenditure ceiling cap across both programs. Once the spending limit is reached, subsequent DAA purchases would be heavily rebated to a nominal net cost as low as pennies per unit.¹⁷

In June 2019, Louisiana signed an agreement with Asegu Therapeutics, LLC, a subsidiary of Gilead Sciences, Inc., for Asegu to provide an unlimited amount of its HCV drug,

UNDER LOUISIANA'S EXPENDITURE CAP AGREEMENT, THE STATE PURCHASES DAAs FOR ITS MEDICAID PROGRAM FROM THE MANUFACTURER AT A NEGOTIATED PRICE THAT UTILIZES ONLY THE FEDERAL DRUG REBATES. DRUGS FOR USE WITHIN THE STATE DEPARTMENT OF CORRECTIONS WOULD BE PURCHASED UTILIZING 340B REBATES TO DISCOUNT THE COST.

Eplclusa, under the negotiated expenditure cap terms as part of a 5-year contract.²⁴ Once a pharmaceutical partner was identified, Louisiana took action to remove its HCV treatment restrictions and facilitate access to DAAs to all persons with HCV who receive state-sponsored health care. Louisiana utilizes this payment model as part of its comprehensive state HCV elimination plan that includes programmatic strategies to improve prevention, screening and treatment, surveillance, provider training, and to expand access to harm reduction services, Louisiana's plan took effect on July 1, 2019.

An important distinction of the expenditure cap is—unlike a true subscription agreement where a set fee is required to be paid before goods or services are received—there is no requirement

that the payer spend the maximum amount under the contract. Payers can purchase DAA treatment at the negotiated unit price, and only trigger the unlimited drug provision if they exceed the cap. This potentiates the opportunity for states not to fully commit the maximum amount of funds towards purchasing treatment, and thus not optimize the opportunity to acquire a greater amount of DAAs. This scheme also provides greater uncertainty of revenue returns to the manufacturer. There is less incentive for both parties to fully invest resources towards the agreement's terms, which could result in not fully achieving the intended public health objectives of maximizing access to HCV treatment.



WASHINGTON'S VALUE-BASED MODEL

Concurrent with Louisiana's efforts to draft and implement its payment model, the state of Washington released a Request for Proposals (RFP) in January 2019 to implement a model as an integral component in its comprehensive statewide *Hep C Free Washington* elimination strategy. Like Louisiana, Washington's plan envisioned a capitated amount the state would be required to spend on DAA purchases before the manufacturer would continue to provide an unlimited amount of the drugs for a nominal price in order to bypass the need for a CMS waiver.^{25,26} Washington elected to secure a **value-based state plan** amendment approval from CMS

to allow it to utilize supplemental rebates to negotiate a low DAA price for the Medicaid program with a manufacturer. Value-based purchasing relies on drug effectiveness rather than volume purchased, and allows the state to negotiate with the manufacturer on terms such as utilization period and outcomes-based benchmarks. In addition, CMS-authorized supplemental rebates that pharmaceutical manufacturers pay to states are exempt from the Medicaid "Best Price" rule, which requires manufacturers to offer the lowest price for a non-generic drug they have negotiated with one buyer to all states in the Medicaid program.²⁷

In Washington's RFP, the state planned to negotiate with manufacturers for a low guaranteed net per unit price (GNUP) for the Medicaid program, utilizing both standard Medicaid rebates and supplemental rebates.²⁸ Like Louisiana, it included specific requirements for the manufacturer to provide support for outreach services as part of the state's comprehensive elimination strategy to increase screening, linkage to care, and treatment.²⁸ Washington also sought, however, to negotiate a GNUP for not only its Department of Corrections, but for all other state entities other than Medicaid that purchase DAAs directly, including the public employees benefits program, state hospitals, and workers covered by the state's worker's compensation system. The state's ability to streamline price negotiation across agencies is due to a prescription drug program enacted by the state legislature in 2003 that consolidated state agencies under one

WASHINGTON'S VALUE-BASED MODEL ALLOWS THE STATE TO UTILIZE SUPPLEMENTAL REBATES TO NEGOTIATE A LOW DAA PRICE FOR THE MEDICAID PROGRAM WITH A MANUFACTURER. VALUE-BASED PURCHASING RELIES ON DRUG EFFECTIVENESS RATHER THAN VOLUME, AND ALLOWS THE STATE TO NEGOTIATE WITH THE MANUFACTURER ON TERMS SUCH AS UTILIZATION PERIOD AND OUTCOMES-BASED BENCHMARKS.

WASHINGTON'S PROPOSAL SOUGHT TO NEGOTIATE A GUARANTEED NET PER UNIT PRICE (GNUP) FOR THE STATE MEDICAID PROGRAM, THE DEPARTMENT OF CORRECTIONS, AND ALL STATE ENTITIES THAT PURCHASE DAAs DIRECTLY, INCLUDING THE PUBLIC EMPLOYEES BENEFITS PROGRAM, STATE HOSPITALS, AND WORKERS COVERED BY THE STATE'S WORKER'S COMPENSATION SYSTEM.

prescription drug consortium, thus allowing it to negotiate with one vendor on behalf of all state agencies.²⁰ Another distinct component of the Washington RFP was a phase two stipulation that once the state met its initial treatment target among those covered by state-sponsored health care, the contracted manufacturer would allow other payers—such as private and commercial insurers—from both within Washington and other states to purchase DAAs under the terms of the agreement.²⁸ Similar to the expenditure cap model used in Louisiana, the Washington contract does not require the state purchase up to the maximum expenditure amount. As the state has already negotiated a low per unit cost, it is less incentivized to spend up to the maximum amount, thereby not guaranteeing that the number of DAA doses purchased matches the full extent of need.

In July 2019, Washington commenced a 4-year agreement with AbbVie, Inc. to provide the DAA Mavyret as well as outreach support services.^{25,26} These services include healthcare personnel training on treating HCV and the Elimination Awareness Bus, a mobile unit that travels and tours across the state, especially to disproportionately impacted areas, providing HCV screening, counseling and linkage to care.²⁹ In contrast to how the specific details between Louisiana and Asegua were made available to the public by releasing the signed contract, the signed contract of Washington with AbbVie, detailing the payment model, is not yet readily available to the public.²⁵ Washington officials, however, have explained the contract's provisions in broad terms. Under this contract, Washington aims to spend about the same amount of money per year while treating twice the number of persons treated in 2018 (approx. 3,300 people), that is “more than \$321 million to treat about 30,000 persons over four years, with options for two-year extensions.”²⁶

EMERGING IPM IMPLEMENTATION



MICHIGAN

On January 29, 2020, Governor Gretchen Whitmer announced Michigan's commitment toward HCV elimination, including seeking policy solutions to low prescription drug costs.³⁰ Accordingly, Michigan released the *We Treat Hep C Initiative* on July 28, 2020, that aimed to increase access to lifesaving therapies by reducing the cost of HCV drugs.³¹ Building upon currently implemented IPMs of Louisiana and Washington with expenditure caps, Michigan released a RFP in August 2020, asking for partnerships to explore discounted drug costs to treat an estimated 38,000 people infected with HCV who are covered by Medicaid and the Michigan Department of Corrections. In early 2021, the state entered into an agreement with AbbVie to use Mavyret as the

state's preferred HCV medication.³² Effective April 1, 2021, Michigan Medicaid removed all prior authorizations to prescribe Mavyret for HCV treatment, but prior authorization is still required to prescribe a person a different DAA.³³

IPM PROGRESS TO DATE

Public health interventions of such significant scale as these require effective means of collecting and analyzing outcomes data to monitor efficacy of existing strategies and to identify and remediate deficiencies. The data should be updated regularly, and include general counts and demographic information on the number of persons treated, as well as more granular data such as rates of diagnostic testing and treatment initiation among people who use drugs (PWUD) and in state corrections, post-treatment SVR, and retention along the care cascade to monitor progress towards elimination. These data should be publicly available, as public access to outcomes data can improve community investment and support for the initiative, and provide readily accessible evidence of program benefit to share with legislators and other stakeholders in order to garner additional support. Public data updates also hold the agency accountable to putting forth the effort and resources needed to achieve desired outcomes.

Despite both plans being in Year 2 of implementation, there is a significant difference in the availability of publicly available data on the ongoing progress between Louisiana and Washington's IPM initiatives.

LOUISIANA

The LDH provides a regularly updated, public-facing dashboard website with data on the number of persons treated since the program's inception, and other basic demographic and location information. Under the contract, Louisiana indicated the intent to treat 10,000 Medicaid beneficiaries and people in prisons by the end of 2020.³⁴ According to data made available on the HCV data website (last updated on June 10, 2021), 8,489 people have accessed treatment since the program started on July 15, 2019.³⁵ The definition of "treated" includes people who have had at least one DAA claim filed since the program start date. Data are obtained from pharmacy claims from Medicaid or the L.A. Office of Public Health Pharmacy for the corrections population. The definition does not include lab results from an SVR-12 test that indicates cure. Additionally, Louisiana reports aggregate numbers of persons treated and does not separate by Medicaid and the correctional system. At the start of the *Hep C Free LA* program, the number of persons starting treatment increased from 288 (in quarter 2) to 1,584 (in quarter 3).³⁵ In 2020, 1,132 persons started in quarter 1, 604 in quarter 2, and 807 in quarter 3.³⁵

The data also does not address continuity of care, thus providing no insight on how many people who initiated treatment successfully completed the treatment regimen and achieved cure. In any event, the total number of persons "treated" is still under the proposed 10,000 goal, but it is reasonable to infer that restrictions related to the COVID-19 pandemic may be a primary factor to this stunted progress.

WASHINGTON

Washington has no public data currently available about the impact of this payment arrangement on access to treatment and progress towards meeting its stated objective of treating 7,500 people per year. Thus, there is little information available to give the public a reliable understanding of what strategies are being implemented or their efficacy.

A public-facing data platform provides for greater accountability for the state to meet established outcomes, such as testing and treatment goals, and would give Washington's residents, legislators, and other stakeholders confidence and motivation to continue to support these initiatives. It is understandable that the significant impact the COVID-19 pandemic had on the state's public health response to HCV had an effect on releasing this information, as many personnel and other resources normally dedicated to HCV were diverted to assist the COVID-19 efforts. As the agency returns to normal operations, this data may be made available.

MICHIGAN

While Michigan's IPM is in its beginning phases of implementation, it seems similar to these existing subscription-like payment models. That is, the *We Treat Hep C* initiative seems to largely focus on reducing HCV drug costs. The proposal mentions bringing together diverse and multidisciplinary steering committees to inform strategy on HCV prevention, clinical capacity, and data and evaluation. Per the proposal, the steering committees intend to "distribute a survey to clinicians to help better understand barriers to HCV testing, linkage to care, and treatment."³⁰ It is unclear how this survey is being disseminated but it is available online.³⁶ Michigan released their state HCV elimination strategy in April 2021, and among its core priorities are increasing HCV testing, and facilitating increased access to treatment by removing all Medicaid prior authorizations for HCV treatment as of April 1, 2021.³⁷

THE FUTURE OF INNOVATIVE PAYMENT MODELS AND HCV TREATMENT: LOOKING AHEAD

EXISTING MODELS FALL SHORT OF ACHIEVING TRUE POTENTIAL

The modified subscription models proposed and implemented by Louisiana and Washington are innovative attempts to reduce the cost of HCV drugs and increase access to care. It is important to note, however, that while a step in the right direction, these arrangements fall short of optimizing the potential for treatment distribution that could be realized under a true subscription scheme. The expenditure cap models do not initially offer unfettered access to the otherwise costly HCV drugs.³⁸ Instead, the quantity of drugs the state will be able to access is contingent upon whether the state has sufficiently appropriated the funds to reach the spending cap, or if other budget constraints preclude the state from spending enough to trigger the unlimited access threshold. States can elect not to spend up to the cap amount during the designated timeframe, not only limiting the amount of drugs it has accessible to prescribe, but also creating revenue uncertainty for the manufacturer. In the absence of strong motivating fiscal incentives for both contracting parties to optimize care—which is the intent of true subscription models—the benefit these models lend to improving HCV treatment outcomes is substantially lessened.

The consolidated prescription drug consortium in Washington is a beneficial component that fosters improved access to treatment for more people, and provides the state the leverage of stronger buying power during negotiations with bidders. States considering implementing an IPM should consider the benefits of such a procurement scheme to streamline purchasing and optimize treatment access. In December 2020, Texas released

THE FUTURE OF INNOVATIVE PAYMENT MODELS AND HCV TREATMENT: LOOKING AHEAD

EXISTING MODELS FALL SHORT OF ACHIEVING THEIR FULL POTENTIAL

- **Expenditure cap models** do not initially offer unfettered access to the otherwise costly HCV drugs. Instead, the quantity of drugs the state will be able to access is contingent upon whether the state has sufficiently appropriated the funds to reach the spending cap, or if other budget constraints preclude the state from spending enough to trigger the unlimited access threshold. States can elect not to spend up to the cap amount during the designated timeframe, not only limiting the amount of drugs it has accessible to prescribe, but creating revenue uncertainty for the manufacturer.
- **In the absence of strong motivating fiscal incentives for both contracting parties to optimize care—which is the intent of true subscription models—the benefit these models lend to improving HCV treatment outcomes is substantially lessened.**

PAYMENT MODELS CAN BE A BENEFICIAL TOOL IN A COMPREHENSIVE ELIMINATION STRATEGY

- HCV elimination cannot occur unless existing cases are identified, treated, and cured. Fifty-one percent of people with HCV in the U.S. do not know their status, evincing the urgency of prioritizing screening and treatment efforts.
- Several states have drafted HCV elimination plans highlighting strategies to increase of screening, surveillance, community engagement, patient navigation and care coordination, capacity building, and to address stigma. Yet, funding appropriations to implement these plans are often insufficient to address the state's needs. **Greater access to DAAs will not yield the benefit of increasing the number of people cured if no resources exist to inform people of their risk of HCV and to get them screened and enrolled into Medicaid if they are eligible.**

a feasibility study to determine if the state could utilize an IPM to supply the treatment needs of those eligible for prescriptions covered by state funds.²⁰ It identified its own disjointed procurement structure across state agencies as a barrier to its ability to include state agencies such as its Department of Criminal Justice into a negotiated purchasing plan with its Medicaid program, and sees creating a cross-agency purchasing plan like Washington's as a viable solution.

The evolution of the existing IPMs in the U.S. suggests that the existing statutory prohibition on up-front payment in the Medicaid program and the cumbersome CMS waiver process are primary factors for these states not implementing a true subscription

AS NEW STATES CONSIDER UTILIZING AN IPM, THEY SHOULD STRONGLY CONSIDER SEEKING TO INCORPORATE A TRUE SUBSCRIPTION PAYMENT MODEL INTO THEIR COMPREHENSIVE HCV ELIMINATION STRATEGY

payment model. Yet, the guaranteed financial commitment that accompanies a true subscription model would obligate and incentivize states to prioritize funding and resource allocations for HCV elimination in ways that the current models do not. Such an agreement would require significant budget allocations to meet the contractual terms and would also incentivize states to fund the scope of elimination strategies needed to ensure that the state is testing, treating, and curing as many people as possible and optimizing the benefits of their DAA investment. Therefore, as new states consider utilizing an IPM, they should strongly consider seeking to incorporate a true subscription payment model into their comprehensive HCV elimination strategy. More states expressing interest in these types of up-front payment schemes could motivate CMS to take steps to facilitate such plans in the future. As an alternative to pursuing CMS approval, states can still make a strong commitment to prioritizing HCV elimination by designating a sizeable, multi-year budget appropriations specifically for DAA procurement and collateral elimination efforts needed to successfully achieve their elimination goals. Increased funding from the federal level is also needed to support states' efforts and facilitate a comprehensive federal response to the HCV epidemic. Still, the existing models promise significant improvement to treatment access in their respective states than previously available and offer insights on how other states can adapt them to future implementation.

IPMs can yield great costs savings to the state agencies that they primarily target—particularly state Medicaid pharmaceutical expenditures. Budgetary considerations, however, should not overshadow the fact that the primary purpose of formulating a model is for it to be but one of many strategies a state will implement to prevent further transmission and to increase access and distribution of HCV treatment to as many people as possible. In Medicaid programs, the decreases in pharmacy spending possible under these procurement strategies should be reallocated within the program to support other hepatitis elimination interventions, and not merely seen as an opportunity to reduce subsequent budgetary allocations.

PAYMENT MODELS CAN BE A BENEFICIAL TOOL IN A COMPREHENSIVE ELIMINATION STRATEGY

HCV elimination cannot occur unless existing cases are identified, treated, and cured. Fifty-one percent of people with HCV in the U.S. do not know their status, evincing the urgency of prioritizing screening and treatment efforts.³⁹ Several states, including Louisiana, Washington, and Michigan have drafted elimination plans highlighting strategies

HCV ELIMINATION CANNOT OCCUR UNLESS EXISTING CASES ARE IDENTIFIED, TREATED, AND CURED

to increase of screening, surveillance, community engagement, patient navigation and care coordination, capacity building, and to address stigma.⁴⁰ Yet, funding appropriations to implement these plans are often insufficient to address the state's needs, and in some instances, such as Washington's elimination plan, the state has made no budget appropriations to fund plan implementation. This creates limited transparency around how the strategies outlined in these plans are being implemented, and what impact they are having in conjunction with the payment models to improve treatment access. This makes it challenging to definitively ascertain whether making HCV drugs more affordable through these models is even increasing access to the drugs and optimizing care.

States should provide more information on how accompanying prevention and outreach strategies are affecting DAA uptake and treatment completion. Strategies outlined in state elimination plans must be adequately implemented for desired elimination outcomes to be realized. Greater access to DAAs will not yield the benefit of increasing the number of people cured if no resources exist to inform people of their risk of HCV and to get them screened and enrolled into Medicaid if they are eligible. Programs are needed to engage those at greatest risk for infection that often faces stigma and can lack awareness of available resources, such as persons who use drugs, to ensure improved outcomes. Information and evaluation data on how these initiatives are being implemented remains fragmented and siloed, creating missed opportunities for states to learn from each other and adapt their strategies to employ best practices. State elimination activities should include robust data collection and surveillance components to measure progress, identify needs, and provide accurate data that can be shared with other entities on prevalence and most effective practices.

It cannot go unmentioned that adequate funding at both the state and federal levels for viral hepatitis elimination strategies undergirds all the recommendations mentioned above. No plan will be successful without the committed efforts of the legislature, health leaders, and the public to prioritize and allocate fiscal and workforce resources to elimination efforts. IPMs, especially those with expenditure cap triggers, require the full commitment of needed funds to actualize the desired treatment outcomes.

STRATEGIES OUTLINED IN STATE ELIMINATION PLANS MUST BE ADEQUATELY IMPLEMENTED FOR DESIRED ELIMINATION OUTCOMES TO BE REALIZED.

CONCLUSION

The modified subscription models proposed and implemented by Louisiana, Washington, and Michigan are innovative attempts to reduce the cost of HCV drugs and increase access to care. Yet, any such plan must be accompanied by a comprehensive strategy to increase resources for prevention, testing and linkage to care to achieve the ultimate goal of reducing cases of HCV and eliminating it as a public health threat.

The variability of commitment and financial investment permitted through these existing purchasing mechanisms do not make them a consistent and reliable tool for increasing access and distribution of DAA treatment. Subsequent state plans seeking to implement an IPM should implement a true subscription model or incorporate additional terms into the agreement with the manufacturer to obligate the state to purchase enough courses of treatment to meet all of the needs of the covered populations.

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