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Policy Brief:

A novel strategy for increasing access to Hep C treatment for Medicaid beneficiaries

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Introduction

Hepatitis C kills more than 20,000 Americans each year, more than the other 60 deadly infectious diseases combined.¹ Most hepatitis deaths occur among adults in their prime working years—ages 45 to 64—compounding the already devastating social toll of the disease.

The good news is that hepatitis C is now curable with just three months of one of a few new and easily-tolerable treatments. With a cure in hand, the prospect of eliminating the scourge of hepatitis C is real. Recognizing this issue, the Centers for Disease Control, the nation's health protection agency, requested the National Academies of Sciences, Engineering, and Medicine to convene a committee of experts to develop a national strategy for the elimination hepatitis C as a public health problem.

The National Academies report concluded that treating all hepatitis C patients could avert near 30,000 deaths and reduce incidence of hepatitis C 90% by 2030.² To meet this goal, the committee advocated treating everyone with the new treatment regimen, without regard to their disease stage. However, the report acknowledged that treatment can cost tens of thousands of dollars for each patient, making it unaffordable for most patients and public and private insurers.

The problem is most acute for the most vulnerable populations. There are roughly 700,000 people in state Medicaid programs and prisons who are eligible for treatment, but only about 20,000 (less than 3%) will receive treatment each year.^{2,3,4} This is due partly to the restrictions imposed by many states on accessing the drug, including requirements that (contrary to National Academies report) require Medicaid beneficiaries to have a certain state of fibrosis (liver disease), restrictions on who may prescribe the hepatitis C treatment, or bans on patients with histories of alcohol or substance use.⁵ These restrictions are not justified by clinical guidelines; states impose these restrictions primarily to limit the impact on their budgets.⁶

The high prices of these new medicines exist mainly because the federal government grants drug manufacturers a period of market exclusivity through the issuance of patents. One option for reducing prices and improving access is for the federal government to take back the patent protection afforded to manufacturers of hepatitis C cures, thereby enabling production of generic versions of the drugs. Such a move, however, is both undesirable and unlikely because it would have a chilling effect on innovation, meaning fewer cures in the future. This raises the policy dilemma: How can we improve access to hepatitis treatment without jeopardizing future cures?

The National Academies report offers a way out of this policy dilemma. It recommends a voluntary transaction between the federal government and a pharmaceutical company, wherein firms producing hepatitis C treatments compete to license their patents to the federal government for use in low-income, vulnerable patient populations, such as those served by Medicaid. Once the federal government purchases the rights to a patent, generic manufacturers may produce the drug for supply to Medicaid and prisons.²

Since the publication of the National Academies report there has been limited interest at the federal level in brokering this deal on behalf of Medicaid programs. However, some states have expressed interest in increasing access to pharmaceuticals without increasing Medicaid budgets. A recent paper

published by the authors of this report in the *Annals of Internal Medicine* proposes a novel strategy for increasing access to hepatitis C treatments in the Medicaid program.⁷ This novel state-level strategy is inspired by the National Academies recommendation; just like the National Academies recommendation it increases access to treatment by proposing a novel contracting strategy. The National Academies recommendation relies on licensing patents; the strategy proposed in the *Annals of Internal Medicine* paper avoids this complication by contracting with a patent holder to obtain the drug for a defined population. The National Academies recommendation targeted federal policymakers with a federal-level solution, but the novel strategy targets state policymakers, allowing each state to negotiate on behalf of its Medicaid beneficiaries.

In the remaining sections, we describe the novel state-level strategy in greater detail. We discuss its implications for different stakeholders—states, Medicaid beneficiaries, and pharmaceutical firms—and discuss legal challenges in implementing this novel strategy and ways to address them.

The Strategy and Its Implications

Status Quo

Consider a state that has about 250,000 Medicaid patients with hepatitis C infection, but only 6,000 receive the new treatment each year due to strict eligibility criteria. Further assume that there are three pharmaceutical firms (firms A, B, and C) providing treatment to patients. Each firm charges approximately \$80,000 per patient, and the state receives a rebate from the manufacturers of \$40,000 per treatment, for a net cost of \$40,000 (while the \$80,000 is charged to the pharmacy or provider that acquires the drug, these costs are passed through to the state Medicaid program, which pays based on the provider's actual acquisition cost). In addition, the state pays \$100 in dispensing fees per patient. The state has a federal Medicaid matching rate of 50%.¹ Firm A is dominant in the state's program and 4,000 patients receive its treatment. The other two firms control a smaller share of the Medicaid market and only 1,000 patients each receive their treatments. Finally assume that the manufacturers' actual cost of producing and distributing the drug to pharmacies is \$200 per patient.

Under this status quo the federal and state governments are spending a combined \$240 million on drugs (\$40,000 x 6,000) and spending \$600,000 on dispensing fees (\$100 x 6,000). Assuming a federal matching rate of 50% these expenditures are split evenly between the federal and state governments with each spending \$120.3 million. The revenues of firm A are \$160 million and the revenues of firms B and C are \$40 million each. Profits of the firms are approximately equal to their

¹ A 50% matching rate is used here for illustrative purposes only. The precise division of costs between state and federal sources for Medicaid expenditures will vary based on the applicable matching rate for the state and for the services, and would take into account factors such as whether the individual is part of the Medicaid expansion population. In addition, a portion of the drug rebates paid to state Medicaid programs are directed to the federal government and not shared with states at the normal match.

revenues given that production and distribution costs are low relative to price; profits of firms A, B, and C are \$159.2 million, \$39.8 million, and \$39.8 million respectively.

The Novel Strategy

The state negotiates with a manufacturer to pay the manufacturer an upfront lump sum amount that is equal to or lower than the state's current total Medicaid spending on all hepatitis C drugs. Subsequently, each time a beneficiary obtains the drug from a pharmacy, the state incurs an expenditure to reimburse the pharmacy's acquisition cost of the drug plus the dispensing fee. This triggers a rebate obligation from the manufacturer. Under the novel strategy, the manufacturer pays the state a rebate equal to 100% of the drug cost. The state shares the cost of its expenditures, net of any manufacturer rebates, with the federal government. Because the rebates offset the full amount of the drug cost, Medicaid programs may take steps to expand the availability of hepatitis C drugs to patients without risk to their budgets.

In the box below, we provide an illustrative example where the state makes a deal with firm A for a lump sum payment of \$200 million. We assume that after the deal is made the state is able to expand its treatments for Drug A to 20,000 Medicaid beneficiaries. We further assume that 100 people continue to be treated with Drug B and Drug C, respectively, as Drug A might not be indicated for some patients. Under this scenario, the spending by the state and federal government is \$200 million for the lump sum payment to firm A, \$4 million in payments to firms B and C each, and \$2 million in dispensing fees. The total spending on hepatitis C treatment under this scenario is \$210 million – a savings of \$30 million compared to the status-quo. Concurrently, the number of people receiving treatment increases more than threefold, from 6,000 to 20,000. Finally, the profits of the firm that secured the deal increase from \$159.2 million to \$196 million and profits of the firms that lost decrease from \$39.8 million to less than \$4 million.

Illustrative flow of funds under novel strategy

Suppose the state makes the deal with firm A for a lump sum payment of \$200 million. The state pays firm A \$200 million. Through a Medicaid waiver or another appropriate federal approval process, and assuming a 50% federal matching rate, the state receives a \$100 million federal matching payment.

When a patient is dispensed Drug A, the state initially incurs an expense for payment of \$80,000 for drug acquisition and a \$100 dispensing fee to the pharmacy. Firm A then pays the state a rebate of \$80,000. The state's Medicaid expenditure and claim for federal matching funds is reduced to reflect the rebate, such that the state and federal government each incur a net cost of \$50 for the dispensing fee.

Suppose 20,000 patients receive Drug A, 100 patients receive Drug B, and 100 receive Drug C. The total state expenditures are \$100 million to firm A, \$2 million each to firms B and C, and \$1 million in dispensing fees. Federal government expenditures are identical given the 50% matching rate. Thus, the state and federal government each spend \$105 million under the novel strategy, resulting in cost savings of \$15 million each relative to the status quo. At the same time the number of people receiving the treatment regimen increases more than threefold from 6,000 per year to 20,000 per year. Finally the profits of the firm that made the deal with the state increase from \$159.2 million to \$196 million.

Why Does the Novel Strategy Lower Costs and Expand Access?

The novel strategy simultaneously lowers government expenditures at both the state and federal levels and dramatically expands access to hepatitis C cures. It does so by exploiting market competition between firms in a voluntary transaction. Under the status quo, firms negotiate with Medicaid to set prices. When negotiating prices, a firm's goal is to maximize revenues or profits. However, high prices increase the cost of providing access to the drug to additional patients. Thus, under the status quo of "price-based contracting," higher firm profits mean reduced access. The novel strategy of "revenue-based contracting" breaks this link between profits and access. Firms can increase profits by negotiating a higher lump sum payment. But once a lump sum payment is set, the state's cost of providing drugs to additional patients is close to zero as the unit price of the drug is zero. Thus, firms are able to increase profits without limiting access.

The novel contracting strategy can simultaneously lower costs and expand access if three conditions are met: (1) the state obtains a deal for a lump sum payment lower than total current spending on all drugs, (2) the state is able to expand treatment, and (3) the state steers utilization from non-preferred drugs (with high unit price) to the preferred drug (with zero unit price). Below we explain why these conditions are likely to be met in a novel strategy scenario.

The lump sum at which a state makes the deal will depend on the degree of competition between the pharmaceutical firms and the negotiating skills of the state. Given that this is a voluntary transaction, firms will only enter negotiations and compete with each other if the expected profits from securing the deal exceed the expected profits from not participating in negotiations. A company that participates in the negotiation and wins the deal will capture most of the state's Medicaid market.

The winning firm will also create goodwill as it will be seen as expanding access to a hepatitis C cure for vulnerable populations. Firms that do not participate in negotiations or firms that are not chosen for the deal risk losing their current Medicaid business. We believe that this risk of losing current business will encourage all firms to participate in negotiations and compete with each other, resulting in savings for the state. If firms use profits under status quo as a reference point for negotiations, then firms with lower market share under status quo will likely accept a lower lump sum payment. Thus, making the deal with firms with lower market share will likely result in higher savings. The lump sum payment will also depend on the value of the treatment with states willing to pay more for treatments with: (1) higher cure rates, (2) fewer or lesser side effects, and (3) greater number of people from whom the treatment is indicated as first-line therapy. Finally, the cost savings might be higher if states can negotiate multiple year deals as it reduces risks for firms and locks in firm profits for multiple years. However, multiple year deals increase risks for state. For example, the state might find new information about side effects of the drug after signing a multiple year deal.

As noted in the introduction, there is tremendous potential to increase treatment; as currently the vast majority of Medicaid beneficiaries with hepatitis C are not receiving treatment. Expanding treatment first requires removing restrictions on treatment eligibility imposed by most Medicaid programs. These treatment restrictions are not consistent with treatment guidelines and are primarily imposed to save costs. Expanding treatment also requires the state and other stakeholders to ramp up efforts for testing and linkage to care. This is certainly feasible and states have demonstrated the ability to significantly expand treatment for other diseases such as HIV. The NAS report suggests several promising approaches and interventions for expanding access to hepatitis C testing and treatment.

To achieve cost savings, a state Medicaid program must also steer demand toward the preferred drug. If a state makes the deal with firm A, the state's cost of providing treatment to one additional patient with drug A is close to zero. But the state's cost of providing treatment to one additional patient with drugs B or C is \$40,000. Thus, in order to achieve cost savings, patients who are indicated to take Drug A must take Drug A rather than its substitutes. States can implement strategies such as prior authorization (need approval from Medicaid before initiating treatment with Drugs B and C) and step therapy (first try treatment A and then others) to identify patients for whom the preferred drug (drug A in this example) is appropriately indicated and direct their treatment accordingly toward the preferred drug.

In summary, the magnitude of cost savings for the state and health benefits for Medicaid beneficiaries from the deal will depend on:

- state negotiations with pharmaceutical firms – which firm secures the deal and whether the deal is single year or multiple year;
- the extent to which the state can expand treatment, as an increase in treatment would prevent downstream morbidity and mortality costs of Hep C and would also reduce incidence of Hep C;
- the extent to which the state can steer utilization towards the preferred drug away from other drugs; and
- the characteristics of the preferred drug.

Comparison with National Academies Recommendation

The novel contracting strategy proposed here and the National Academies recommendation for expanding access to treatment have several similarities. First, both focus on “revenue-based contracting.” Under both solutions the government makes a lump sum payment to firms and after the lump sum payment is made, the unit price of the drug is close to zero. Second, both focus on the Medicaid market where government is the payer and beneficiaries have limited access to the drug. Despite these similarities the two solutions differ in important ways. The National Academies recommendation relies on licensing patents; the strategy proposed here avoids this complication by contracting with a patent holder to obtain the drug for a defined population. The National Academies recommendation targets federal policymakers with a federal-level solution, but this strategy targets state policymakers allowing each state to negotiate on behalf of its Medicaid beneficiaries. Thus, the strategy proposed here does not create a winner-take-all market: some states might strike a deal with one firm while other states might strike deals with other firms. In contrast, under the federal patent licensing approach, firms may be reluctant to participate out of concerns that they may lose their intellectual property or related products or non-Medicaid markets. In addition, the federal approach to purchasing patent licenses would lock-in states to one preferred drug for multiple years until the patent expires in 2029 or beyond. The state-level solution avoids patent licensing and multiple year lock-in. Deals can be annual or multiyear depending on the interest of the state and pharmaceutical firms.

Implementation Challenges

In this section we discuss potential implementation challenges that arise from this novel strategy. While some challenges exist, the novel strategy is feasible. Implementing it would require leadership at both the state and federal levels.

Would the Lump Sum Payment be an Eligible Medicaid Expenditure for Federal Matching?

The lump sum payment would not be a typical “medical assistance” expenditure eligible for federal financial participation, since it is not a patient-specific expenditure nor is it a payment to the provider of the actual service, *i.e.*, to a pharmacy for providing and dispensing the prescribed drug to the Medicaid beneficiary. “Medical assistance” is defined in section 1905(a) of the Social Security Act as “payment of part or all of the cost of the [statutorily enumerated] care and services...” for Medicaid beneficiaries; “prescribed drugs” are a service included in the statute as medical assistance. The lump sum payment made to a drug manufacturer, while not a typical expenditure, could arguably be regarded as a payment for the cost of treatment.

To obtain federal matching funds for the lump sum payment, a state would need to obtain approval from the federal agency that oversees Medicaid: the Centers for Medicare and Medicaid Services, known as CMS. Each state implements its Medicaid programs pursuant to the terms of its federally

approved state plan, which, among other things, sets forth the scope of the state's program and applicable expenditures and payment methodologies. If CMS agrees that the hepatitis C treatment rebate strategy and associated lump sum payments qualify under Medicaid law as medical assistance, a state would need to submit and receive federal approval for an addition or amendment to its state plan that implements the novel rebate approach.

If CMS takes the position that the lump sum payments do not constitute "medical assistance," CMS may grant a waiver pursuant to its demonstration project authority under section 1115(a) of the Social Security Act. This section permits CMS to waive a state's compliance with various program requirements and to treat the costs "which would not otherwise be included as expenditures under ... section 1903 [of the Social Security Act]" as "expenditures under the State plan ... as may be appropriate." CMS could approve a state application for a section 1115(a) demonstration project if it finds that it "is likely to assist in promoting the objectives of" the Medicaid program. Section 1115(a) demonstration projects have been approved for periods of up to five years. Such an 1115 demonstration project approval could allow a state to receive matching funds for a lump sum payment that covers more than one fiscal year.

In connection with its discussions with CMS, a state would need to determine the federal matching rate applicable to the lump sum payment. For example, states that have expanded their Medicaid program would wish to ensure that the enhanced federal matching rate available to medical assistance expenditures for the Medicaid expansion population can be applied to a portion of the upfront payment.

In addition to the federal issues, state law likely would be needed to authorize the state Medicaid agency to negotiate and make the lump sum payment. Existing state legislative authority might not allow payments that are not direct expenditures for medical assistance.

Will the lump sum payment and subsequent rebates affect Medicaid Best Price in other states?

Under the federal Medicaid Drug Rebate Program (Social Security Act §1927), the amount of a manufacturer's required rebate to Medicaid programs is based on its reported pricing data that includes its best price offered for the drug. The proposed lump sum arrangement could be structured to not have an impact on a drug's Best Price. CMS regulations define Best Price to mean "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure" (42 C.F.R. § 447.505(a)). A discount granted to a state can implicate best price, but for two regulatory exceptions. First, rebates made to a state Medicaid agency pursuant to the national prescription drug rebate agreement do not affect best price. Second, amounts made to a state Medicaid agency under a CMS-authorized supplemental agreement are also exempt from best price

(42 C.F.R. § 447.505(a)(7)). Therefore, if the state secures CMS approval of the 100% rebate arrangement, the rebates should not have best price implications.

Will the lump sum payment and subsequent rebates violate federal Anti-Kickback Statutes (AKS)?

A participating manufacturer may wish to consider the potential for the arrangement to inadvertently create risk under the federal Anti-Kickback Statute (AKS). The AKS makes it a crime for an individual to either solicit, receive, offer, or pay remuneration as a condition of referring an individual to a person for the furnishing or arranging of an item or service for which payment may be made under a federal health care program (Social Security Act § 1128B(b)).

The agreement to pay rebates to the state is, on its face, an offer of remuneration in exchange for the state's assistance in increasing the availability of the manufacturer's products for which payment may be made under the Medicaid program, and therefore could be construed as a violation of the AKS. However, the arrangement arguably does not raise the concerns generally associated with the AKS, as the payments would not be made—directly or indirectly—to the professionals who order or refer the drugs in question. Additionally, the proposals should not increase overall costs to federal and state health care programs, but should reduce them. However, in structuring the arrangements, states and manufacturers may wish to consider potential risk under the AKS and attempt to align the arrangement with potentially applicable safe harbors (such as the discount safe harbor, 42 C.F.R. § 1001.952(h)), to the extent possible. Manufacturers may also wish to solicit an advisory opinion from the HHS Office of the Inspector General (OIG). This would allow the parties to ensure that safeguards are in place to protect them from potential liability under the AKS or other fraud and abuse statutes.

Can the Novel Strategy be implemented by states with high Medicaid managed care penetration?

Yes, the novel strategy could be advantageous even in states where drugs costs are reimbursed through Medicaid managed care plans. Options could include adjustments to plan capitation rates to reflect the expected utilization of hepatitis C drugs, or to carve out the hepatitis C drugs from its managed care contracts. If a state includes hepatitis C drugs in the scope of its managed care contracts, it would need to require the plan to take steps to ensure the availability of and access to the drugs from the state's preferred manufacturer. The state may either increase the capitation rates to reflect plan costs associated with this new utilization or make arrangements with the managed care plan to benefit from the rebates paid by the winning firm. A carve out, on the other hand, would allow the state to directly establish parameters for beneficiary access and appropriate clinical treatment of the drug in the fee-for-service program and would lower rates paid in the managed care program.

May a State impose restrictions on the use of drugs in the class that are not subject to the lump sum payment arrangement?

Yes, a state may impose restrictions on the use of other drugs through the use of prior authorization. Section 1927(d)(1)(a) allows states to create prior authorization programs subject to the requirements of subsection (d)(5). That requires timely review of prior authorization requests. It is likely that a state will have to submit a State Plan Amendment to CMS setting forth the new prior authorization requirement based on the lump sum payment arrangement. It may also be necessary for the state to gain the authority to impose prior authorization based on the lump sum payment arrangement.

Can this idea be implemented for increasing access to drugs for other state programs?

The lump sum payment arrangement could raise additional complications if a state desires to negotiate sales for use in other state programs and for populations that are not reimbursed by Medicaid. For example, a state may wish to enter into an arrangement under which the manufacturer is required to provide rebates to the state for drugs provided to state and local prison inmates, or for its residual uninsured populations. If such a requirement is agreed to as a condition of the lump sum payment, the state may not be able to receive federal financial participation under the Medicaid program for the full amount of its expenditure on the lump sum payment.

The state potentially could obtain federal approval for a section 1115(a) demonstration, as discussed above, by justifying the inclusion of non-Medicaid programs and populations in the arrangement as necessary for its success in promoting Medicaid objectives. Alternatively, a manufacturer and state could agree – separately from any Medicaid arrangement – for a similar lump sum arrangement for the additional programs and populations. However, absent federal support such an arrangement risks setting a new Medicaid Best Price.

Conclusions

The novel hepatitis C treatment purchasing strategy proposed in this paper coupled with increased testing and linkage to care has the potential to dramatically increase access to hepatitis C drugs in the Medicaid program without increasing state and federal costs. Implementing this strategy poses some challenges, but they are surmountable. States that pursue this novel strategy for improving access to hepatitis C treatments will likely see improvements in health and reductions in downstream costs associated with hepatitis C morbidity and mortality. We can eliminate hepatitis C in the US if several states can successfully implement this strategy.

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