

Potential Strategies to Better Control Rising Pharmaceutical Costs October 25, 2016

Goal: Take state action to better control pharmaceutical costs which are among the fastest growing components of health care cost.¹

Recommendation: While a state's power to impact pharmaceutical costs is relatively limited, it is recommended that the state pursue three separate, but related strategies to better control prescription drug costs.

1. Strategies to better understand drug pricing

Because of the complexities of and lack of understanding around manufacturing costs and pricing methodologies, purchasers are at a significant disadvantage in negotiating agreements with insurers, pharmacy benefit managers and manufacturers regarding prescription coverage. There is a clear need for the state to promote transparency regarding pricing and industry practices that impact pricing by implementing the following strategies:

- A. Consistent with other transparency strategies, enhance the Attorney General's powers to investigate the pharmaceutical industry with respect to manufacturing costs; pricing and reimbursement practices; utilization management programs; consumer incentive initiatives; the contractual relationships involving drug manufacturers, PBMs, insurers, TPA, and dispersing pharmacies; pricing practices of hospitals regarding their mark up above the cost of drugs under the federal 340B program. The Attorney General should have the power to subpoena claims data and other needed information in support of the Office's investigational activities to understand key cost drivers and pricing activities.

The Attorney General should be required to produce a report on his or her findings and hold a public hearing to help educate the public's understanding of the dynamics behind drug price increases. The Massachusetts Attorney General issued a report on October 7, 2016 on its findings after its year-long study of drug costs in the state,² which could serve as a baseline for the Connecticut Attorney General to build upon.

- B. Strengthen unfair trade practice laws to address drug pricing at levels not supported by effectiveness pricing studies³ or other benchmark pricing and to address deceptive and

¹ The EXPRESS SCRIPTS LAB, EXPRESS SCRIPTS 2015 DRUG TREND REPORT 27 (Mar. 2016)

² Massachusetts Office of the Attorney General. Examination of Health Care Cost Trends and Cost Drivers Pursuant to G.L. c. 12C, § 17 Report for Annual Public Hearing Under G.L. c. 6D, § 8, October 7, 2016.

³ Creating effectiveness pricing studies is a new area of analysis which is being conducted by the Institute for Clinical and Economic Research³ and others and tries to value a new drug coming onto the market based on the increased benefit it offers to patients using the drug, compared to other new drugs coming

misleading marketing associated with promotion of manufacturer consumer discount coupons for brand drugs and coupons from retail pharmacists offering gift cards to consumers transferring prescription refills to a new pharmacy. ⁴

C. Enact transparency legislation to address the following issues:

- 1) Require Pharmacy Benefit Managers to delineate in their contracts with pharmacists how generic drug maximum reimbursement pricing is calculated, allows the pharmacist to contest the amount paid under the contract and to receive retroactive payment adjustments, as appropriate. ⁵
- 2) Require drug manufacturers to disclose to the Attorney General the following pricing information for up to a specified number of high-expenditure drugs which meet specific pricing triggers, such as 1) list price increases of 50% over the past five years, or 15% over the last year or 2) initial launch prices that exceed the average cost of drugs in the same class by 30%:⁶
 - Total costs of production for specific drugs;
 - R&D costs for specific drugs, including details on R&D paid with public funds;
 - Marketing spending for specific drugs;
 - Different prices charged for the drug, including international rates;
 - Total profit made from specific drugs;
 - Percent of R&D budget spent on basic research;
 - R&D efforts that have not resulted in any approved drugs, and
 - Discounts and rebates provided to insurers and PBMs, including Medicaid providing coverage to Connecticut residents through Medicaid, private insurance programs, the state exchange and 340B programs.

Permit the Attorney General to make this information and his or her findings available to state purchasers, including DSS and the Comptroller's Office, and to policy makers in order to enable more informed program and policy decisions.

onto the market. For more information see: <https://icer-review.org/> ROI pricing bases prices on the estimated long-term savings realized by use of the drug through reduced medical expenses, increased patient productivity, etc. It is in the theoretical stage, but worth monitoring its development and implementation over time.

⁴ Coupons reduce out-of-pocket, but not third-party payer costs. As a result, they can effectively steer patients toward high-priced drugs despite the availability of clinically-comparable, lower-cost alternatives. This action places upward pressure on insurance premiums, which are ultimately borne by the same consumers enjoying these short-term savings.

⁵ Iowa has enacted a similar law. See

⁶ Vermont has enacted a similar law, Vermont Act 165, An Act Relating to Prescription Drugs, which was signed into law June 2, 2016 and focuses on high cost, high volume drugs with significant price increases. The impact of this law on prices has been questioned by policy experts. See, for example: <http://www.forbes.com/sites/theapothecary/2016/06/10/vermonts-wrongheaded-drug-price-transparency-bill-misses-the-mark/#699c24345ed5>

2. Strategies to maximize state purchasing and regulatory powers to reduce pharmaceutical costs

The state is a purchaser of prescription drug coverage principally through its Medicaid and state employee/retiree programs. To maximize the ability to influence prices, the state should implement the following strategies.

A. Medicaid functioning as contractor for pharmacy coverage

- 1) As a participant in a purchasing coalition, Top Dollar Program (TOPS), Medicaid should work with the coalition to adopt performance pricing⁷ in its contracts with manufacturers, and use comparative effectiveness research⁸ in developing its preferred drug list. All Medicaid programs that are participating in TOPS should explore aligning their preferred drug lists, at least among some drug classes, and pharmacy management programs to maximize the coalition's purchasing power.
- 2) Investigate the feasibility of joining with the Comptroller's Office to jointly administer their pharmacy programs in order to increase negotiating leverage.
- 3) Medicaid should continue to review and track CMS' new pricing guidelines and make additional adjustments, as appropriate. Investigate the reimbursement methodology regarding physician purchasing and administration of in-office infusion drugs to maximize drug effectiveness and efficiency.
- 4) Monitor the Washington state and CMS negotiations and consider seeking a Medicaid waiver to enhance flexibility in managing the pharmacy benefit. Options include:⁹
 - I. Seek a waiver of requirements of the Medicaid drug rebate law while maintaining access to the minimum and best-price rebates. Under this option, state Medicaid programs would continue to be guaranteed the

⁷ Performance Pricing involves set final pricing of a particular drug based on whether the drug performs "in the field" as expected from clinical trials. The price is lower if the drug does not perform. The payment model would be based on the nature of the drug and how effectiveness is measured. For example, Cigna negotiated with the manufacturer of a new class of cholesterol-lowering drugs that it would further discount the drug price if the patients taking the drug do not have results as expected, the manufacturer further discounts the cost of the drugs for all patients. The manufacturer of Bortezomib for myeloma pays for drug costs for any patient who fails to respond after four cycles of the drug, because effectiveness will be known by then. There are challenges to pursuing this contracting approach, including the need for significant and sustained purchasing power, a payer with the ability to collect and use both pharmacy and clinical data to implement the payment model, and a drug effectiveness can be measured in a relatively short period of time with clear biomarkers.

⁸ The Drug Effectiveness Review Project (DERP), operated out of the Oregon Health and Science University's Center for Evidence-Based Policy is a key source of evidence based research reports.

⁹ These strategies are included in a new NASHP report on possible strategies for states to impact prescription drug costs. These strategies have not been implemented by any states to date, but at least one state is in discussion with CMS regarding waiving Medicaid requirements. See NASHP's Pharmaceutical Cost Work Group. "States and the Rising Cost of Pharmaceuticals: A Call to Action". National Academy for State Health Policy. October 2016. Available at: <http://nashp.org/wp-content/uploads/2016/04/Drug-Brief1.pdf>

minimum federal rebate and the best-price rebate but they would also be able to employ selective contracting, performance contracting and sole source contracting, etc., to enhance market leverage for better supplemental rebates.

II. Seek a waiver to opt out of Medicaid rebate provisions for a limited number of drug classes. This approach could be used to innovate in specific classes of drugs by employing:

- o New service delivery options
- o A non-Medicaid purchasing pool or state PBM arrangement, or
- o Bulk purchasing of sole source products.

B. State agencies functioning as contractors for pharmacy coverage

- 1) Any state agency issuing RFPs or renegotiating a contract for services with either insurers or with PBMs should include in their RFPs requirements that the vendor -- without increased expenses to the state -- shall a) conduct or fund pharmacoeconomic studies to assess relative effectiveness of selected new drugs compared to existing drugs and to share research findings with the state agency; b) negotiate performance pricing contracts with manufacturers and c) develop the infrastructure for and implements indication-specific pricing.¹⁰
- 2) All state agencies purchasing health care coverage develop the capability and knowledge base to actively manage insurer and PBM contracts by meeting regularly with the vendors to review contracted pricing and rebates, as well as utilization trends, so that they may fully understand current cost drivers, new drug pricing trends, specific cost-saving strategies being employed and to collaboratively identify areas for the vendor to focus its comparative effectiveness research and cost containment activities that focus on maximizing medication effectiveness. Negotiate annual price caps and cost increases with the PBM. Consider moving to PBM contracts that do not link the PBM's profits with the sales volume and cost of drugs that run through the PBM contract.

¹⁰ Indication-specific pricing involves setting different prices for different indications or for distinct patient subpopulations eligible to use the medications, with prices varying based on relative clinical benefit. For example, Express Scripts is seeking differential pricing from manufacturers based on how a cancer drug, Tarceva, is used. Clinical trials have indicated that Tarceva performs better against lung cancer, compared to pancreatic cancer. Currently payment systems are designed to pay the same unit price, regardless of use, for each drug based on a unique identifier. Few payers have the systems in place to join clinical and pharmacy data to differentiate clinical uses. Indication-specific pricing can be implemented when the drug dosage or delivery system is changed to generate a separate unique identifier (e.g., botox for cosmetic purposes vs botox or bladder control).

- 3) The Comptroller's Office should pursue efforts to negotiate manufacturer rebates from its medical plan vendors for infusion drugs administered as a medical benefit by physicians in ambulatory settings.
- 4) Consistent with CMS' policy direction, all commercial insurers, including those administered on behalf of the state's employees and retirees, should negotiate reimbursement arrangements for infusion drugs administered in an ambulatory setting that delink the administration fee from the cost of the drug, thus eliminating any incentives for physicians to use the most expensive drug, when equally effective, lower cost alternatives are available.
- 5) All state agencies verify that they are maximizing the pricing structure of the federal 340B program, and if not, to take steps to do so.

C. State as bulk purchaser

- 1) Following the vaccine purchasing model, enact legislation to empower the state to negotiate bulk purchasing and distribution of key public health drugs, such as Hepatitis C treatment drugs.¹¹ To implement this strategy it would require participation of commercial insurers, which may be difficult to obtain.

D. State as regulator

- 1) Expand the Connecticut Insurance Department's authority to establish requirements for insurers to promote pharmaceutical cost savings and to consider the insurers' effectiveness at doing so as part of the CID's rate review process. Requirements for insurers should include, but not be limited to:
 - I. Use of performance pricing and indication-specific pricing;
 - II. Implementing programs to enhance medication optimization, such as paying clinical pharmacists for therapeutic management services for complex patients and rewarding primary care clinicians for timely medication reconciliation, and
 - III. Implementing reimbursement methodologies for infusion drugs administered in an ambulatory setting that delinks the administration fee from the price of the drug to eliminate any incentives for physicians to use higher priced drugs when lower cost, equally effective drugs are available.
 - IV. Reimburse amounts made to hospitals for drugs purchased by the hospital under a federal 340B program and the level of mark-up the insurers accept.

¹¹ NASHP's Pharmaceutical Cost Work Group. "States and the Rising Cost of Pharmaceuticals: A Call to Action". National Academy for State Health Policy. October 2016.

- 2) Enact legislation similar to California Proposition 61¹² that prohibits state agencies from buying any prescription drug from a drug manufacturer at any price over the lowest price paid for the same drug by the United States Department of Veterans Affairs, except as may be required by federal law. Apply this requirement to any program where the state agency is the ultimate payer for a prescription drug, even if the state agency does not itself buy the drug. The amount of savings will depend on several factors, including the variance between current prices paid and the VA's prices and the willingness of the manufacturers to accept the VA price. The manufacturers could also respond by increasing the VA prices. The requirement would also need to be implemented in a manner that does not jeopardize Medicaid's best-price guarantee.¹³
- 3) Create a public utility model to oversee drug prices. Under a public utility model, the state could create a drug price review board to review, approve or adjust launch prices for all newly-approved drugs, or drugs with list prices above a certain dollar threshold. The board could also review price increases for brand or generic drugs that exceed a certain threshold (e.g., 10 percent for brand-name drugs and 20 percent for generics). As part of this review, the board could hold open hearings, review data submitted by manufacturers and collect other publicly-available information. It could also direct new research to assess the appropriateness of specific launch prices or price increases. The amount of savings would depend on several factors, including the variance between the regulated price and the current price and whether the manufacturer would continue to do business in the state. The initiative would need to be implemented in a manner that did not jeopardize Medicaid's best-price guarantees.¹⁴
- 4) Enact legislation requiring all providers administering biologically based drugs to use biosimilar drugs, whenever available.

3. Strategies to optimize safe and effective use of medications

Medication adherence, which is an important element of maximizing effectiveness, is variable and well below desired levels. Research has consistently found that improved medication adherence can reduce total health care costs by reducing emergency department and inpatient services, even though pharmacy costs have increased.¹⁵ Because drug adherence and the

¹² [https://ballotpedia.org/California_Proposition_61,_Drug_Price_Standards_\(2016\)](https://ballotpedia.org/California_Proposition_61,_Drug_Price_Standards_(2016))

¹³ For an analysis of the potential impact of this proposition on costs see:

[https://ballotpedia.org/California_Proposition_61,_Drug_Price_Standards_\(2016\)](https://ballotpedia.org/California_Proposition_61,_Drug_Price_Standards_(2016))

¹⁴ For a discussion of this strategy see NASHP's Pharmaceutical Cost Work Group. Pages 7-8

¹⁵ M. Christopher Roebuck, Joshua N. Liberman, Marin Gemmill-Toyama and Troyen A. Brennan. "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending" *Health Affairs*. January 2011, Vol 30, No 1, 90-99.

reasons for non-adherence are complex, research has suggested that different approaches are needed based on patient characteristics, clinical conditions and types of interventions.¹⁶

It is also important to note that providing financial incentives through reducing or eliminating co-payments and deductibles for drugs that help control chronic conditions and associated medical services have also found to be effective in increasing adherence, but has not necessarily resulted in total decreased costs.¹⁷

To optimize safe and effective use of medications, the state should implement the following strategies:

- A. Include behavioral health clinicians and clinical pharmacists as members of the Community Health Teams
- B. Expand the funding to primary care practices participating in the PCMH+ initiative and CCOs to cover therapeutic management services by clinical pharmacists
- C. Require all hospitals and nursing homes to adopt the use of a standard discharge form that would include a listing of the patient's prescribed medications and require PCMH+ practices and CCOs to implement protocol standards for community-based providers to complete timely medication reconciliation processes. Charge the Department of Public Health with the responsibility of working with stakeholders to develop the standard discharge form.
- D. Restrict the ability of dispensing pharmacies to do automatic refills because the automatic refills often create waste in the system because changes in prescriptions or discontinuation of prescriptions are not recognized.
- E. Promote the use of eprescribing systems to notify a dispensing pharmacy that a prescription is cancelled.
- F. Promote the use of eprescribing systems to enable pharmacists to electronically communicate with prescribing clinicians regarding requests and questions.
- G. Provide clinical pharmacists and community-based providers, such as home health nurses, with access to relevant clinical information for purposes of assessing effective use of pharmaceuticals.

¹⁶ Meera Viswanathan, PhD; Carol E. Golin, MD; Christine D. Jones, MD, MS; et al. "Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review." *Ann Intern Med.* 2012;157(11):785-795.

¹⁷ Meera Viswanathan, PhD; Carol E. Golin, MD; Christine D. Jones, MD, MS; et al.