Overview

Public Act Number 15-146, Section 17, enacted June 30, 2015, instructed the Connecticut Health Care Cabinet (the Cabinet) to make recommendations on health care cost containment strategies for Connecticut.

In its initial <u>report</u>, released in January 2017, the Cabinet provided detailed health care cost containment strategies, covering a variety of topics. However, the Cabinet did not release final recommendations related to containing pharmacy costs at that time, instead the report included draft concepts to be explored over the course of 2017. Over the last year the Cabinet has engaged a variety of stakeholders including industry experts, government leaders, researchers, consumers, providers, health plans and advocates, to help the identify a set of detailed recommendations.

Over the first half of the year the Cabinet engaged presenters from industry, national experts and other stakeholders in order to better understand the prescription drug market and the factors that are contributing to higher prescription drug costs. In the second half of the year the Cabinet created working groups to develop more detailed recommendations related to prescription drugs with the same overarching goals that drove the prior recommendations regarding medical expenditures which included:

- monitoring and controlling health care costs;
- (2) enhancing competition in the health care market;
- (3) promoting use of high-quality health care providers with low total medical expenses and prices;
- (4) improving health care cost and quality transparency;
- (5) increasing cost effectiveness in the health care market; and
- (6) improving the quality of care and health outcomes.

Each work group developed a charge and list of recommendations relevant to its charge. Detailed recommendations and each work group's charge as well as meeting information can be found here.1 After initial review and consideration of the recommendations of each workgroup the Health Care Cabinet directed the workgroup chairs to collaborate to prioritize the recommendations and combine them into one report to present to the public for comment.

¹ Detailed information from the Cabinet meetings, including presentations, is available at the meetings page here.

This report represents the combined efforts of the various workgroups. It compiles the recommendations of individual work groups into one document and emphasizes the recommendations that the workgroup chairs have determined to be of the highest priority.

Recommendations are organized into two categories; those that require legislation and those that can be implemented using existing administrative authority.

This document and all recommendations included herein are in draft form with the goal of eliciting public comment and feedback. After public feedback has been collected the Cabinet will again consider the recommendations and may change and reprioritize the list prior to sending a final report to the legislature for consideration.

Background

Summary of Selected Pharmaceutical Cost Provisions from Other States

In developing the recommendations, the workgroups, in many cases, leveraged the best thinking in other states, all of which are wrestling with the same problem of rising pharmaceutical costs. Below is an overview of activities in other states as well other helpful resources.

The provisions highlighted here are not exhaustive, they were selected based on subjective criteria including the possibility of passage – i.e., a demonstrated level of traction or success in the public or legislative arena (such as bills that may have passed a state legislature but were vetoed by the governor) – as well as considerations such as the practicality of implementation and potential impact. These judgments are subjective, but are informed by extensive consultation with non-partisan expert organizations, notably the National Academy of State Health Policy (NASHP) and the National Conference of State Legislatures (NCSL).

The highlighted provisions are divided into two main categories. The first category is transparency: provisions that require or encourage the dissemination of information around drug prices and financial arrangements (including rebates) anywhere in the supply chain to either the public, policymakers/regulators, or a third party. The second category is pricing or cost regulation: provisions that involve not just transparency, but some form of active price control, review, or price-setting.

Because of the lack of federal action on pharmaceutical pricing and costs, the issue of drug costs is at the top of the agenda in many states across the country, and there are many worthwhile proposals other than the ones highlighted here. Thus, in addition to the state level actions several additional resources are included – documents such as white papers, lists or searchable databases of state initiatives – created by other organizations, such as NASHP,

discussing or listing many other state provisions targeted to the high cost of pharmaceuticals. These documents and other resources are listed below.

Major New State Drug Cost Laws or Passed Bills

I. Transparency Measures

California

- a. S.B. 17 (law passed)
 - Requires companies to notify health insurers and government health plans 60 days prior to raising prices for a particular drug more than 16 percent over a two-year period. Limited to drugs with wholesale acquisition costs over \$40 per episode
 - ii. Manufacturer must justify the increase
 - iii. Health plans must report the percentage of premiums spent on prescription drugs.
 - iv. Data will include information on how the drug price contributes to premium increases
 - v. Effective date: Jan. 1, 2019
 - vi. Information public: All provided information will be made public
 - vii. Litigation: Yes (PhRMA)

Nevada

- b. S.B. 539 diabetes drug transparency (law passed; Ch. 592)
 - Require PBMs to reveal rebates they get on diabetes drugs such as insulin;
 - ii. Manufacturers & PBMs must report certain costs/profits information
 - iii. Gag clause prohibition: forbids PBMs from preventing pharmacists discussing lower-cost options with consumers
 - iv. Non-profits such as patient advocacy organizations must disclose funding from manufacturers, PBMs and insurers
 - v. PBMs now have fiduciary responsibility to insurers
 - vi. Effective date: different provisions with various effective dates from June 15, 2017 to January 1, 2018
 - vii. Information public: Yes. (Some information is aggregated and/or deidentified)
 - viii. Litigation: Yes (PhRMA & Biotech)

<u>Pennsylvania</u>

- c. H.B. 1464 (did not pass)
 - Requires data reporting on factors that affect a drug's Wholesale Acquisition Cost
 - ii. Calculate financial impact of high drug costs by tracking avoidable medical costs, such as for interventions and hospitalizations caused by patients' inability to afford prescription drugs

Multiple states

- Provisions re determining "excessive" costs (MA SB 652; NJ S. 3088; NY A 5733, OR HB 2387)
- iv. Bills would establish a body (commission or board, etc.) to act on behalf of the state with the authority to determine excessive prices or otherwise make recommendations about drug prices based on data reported by manufacturers

II. Pricing/Cost Measures

California (see Ohio)

- a. Calif. Proposition 61 (2016; proposition failed)
 - i. Would have barred the state from spending more on a prescription than the lowest price paid by the U.S. Dept. of Veterans Affairs.

Maryland

- b. H.B. 631 Price-gouging law (May 2017)
 - Medicaid must notify Attorney General when off-patent or generic drugs experience excessive price increases (50% or more in one year); penalties if increases not justified
 - ii. Drug must cost no more than \$80 for one-month supply
 - iii. Information public: No
 - iv. Effective date: Oct. 1, 2017
 - v. Litigation: yes (generic drug makers; Judge allowed it to take effect Oct. 1, 2017)

New York

- c. Section 280 Public Health Law
 - i. Medicaid drug spending capped at medical inflation plus 5%
 - ii. Requires review of clinical benefit vs. costs

- iii. Dept. of Health to negotiate enhanced rebates with manufacturers if cap is exceeded
- d. Link to webinar and presentation by state Dept. of Health (August 31, 2017):
 https://www.health.ny.gov/health-care/medicaid/regulations/global-cap/2017-8-29-medicaid-drug-cap.htm

Ohio (see California)

- e. Issue No. 2: Proposition similar to Calif. Proposition 61 (failed, Nov. 7, 2017)
 - i. Would have barred the state from spending more on a prescription than the lowest price paid by the U.S. Dept. of Veterans Affairs.

Vermont

- f. Act 165
 - 2016 legislation requires manufacturers to justify price increases determined to be driving up spending in state programs, such as Medicaid.
 - ii. Manufacturers must report drugs with price increases of 15% in one year, or 50% over five years. Requires the state to identify up to 15 drugs that account for significant state spending and which have seen price increases of either 50 percent over five years or 15 percent over one year. Manufacturers of those products have to submit price increase justifications to the Attorney General and that information will be made public.

iii. Information public: Yes

iv. Effective date: June 2, 2016

v. Litigation: unknown

III. Administrative Measures

Louisiana

- a. Invoke federal patent law exception for the public interest for Hepatitis C treatments (May 2017 reports that state health secretary seeking advice from health law experts)
 - i. Proposal to invoke obscure 1910 federal law to allow U.S. to procure generic versions of expensive Hepatitis C drugs. (This federal law, 28 U.S.C. § 1498, allows government when it is in the public interest to itself manufacture or procure patented goods from a third party like a generic

drug maker, so long as the government pays "reasonable" compensation to the patent holder.)

IV. Additional resources

Compilations of State initiatives

- V. State Legislative Action on Pharmaceutical Prices, NASHP's Pharmacy Cost Work Group (updated November 3, 2017)
 - a. Link: http://nashp.org/state-legislative-action-on-pharmaceutical-prices/
 - b. Link to 2017 state legislative action worksheet: https://nashp.org/wp-content/uploads/2016/09/Rx-Legislative-Tracker-11.3.171.pdf
 - c. Link to 2015-2016 state legislative action worksheet: https://nashp.org/wp-content/uploads/2016/09/2016-Rx-Legislation-Tracker.pdf
- VI. Prescription Drug State Database 2015-2017 State Legislation on Prescription Drugs, National Conference of State Legislatures (updated October 23, 2017)
 - a. Link: http://www.ncsl.org/research/health/prescription-drug-statenetdatabase.aspx
- VII. Curbing Unfair Drug Prices A Primer for States, Global Health Justice Partnership Policy Paper, Yale Law School, Yale Sch. Of Public Health, Natl. Physicians Alliance, Universal Health Care Foundation of Connecticut, (August 2017) (this is also a White Paper; see Appendix for legislation spreadsheet)
 - a. Link:
 https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf

White Papers and Other Resources

- VIII. Lowering Drug Costs: Transparency Legislation Sets Off Flurry of New State Approaches,
 Trevor Flynn & Jerin Phillip (NASHP State Health Policy Blog, August 2017)
 - a. Link: https://nashp.org/lowering-drug-costs-transparency-legislation-sets-off-flurry-of-new-state-approaches/
 - IX. States and the Rising Cost of Pharmaceuticals: A Call to Action, NASHP's Pharmacy Cost Work Group (October 2016)
 - a. Link: http://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf

Draft Recommendations

Drawing from many of the resources identified above and informed by presentations to the Cabinet and various workgroups from industry, policy groups and stakeholders the draft recommendations can be found below. The recommendations are divided into two groups,

those that require legislation "Legislative" and those that can be done within existing authority "Administrative". Under each category certain recommendations have been designated priority; the indication identifies those options that were deemed to be both impactful and plausible.

All recommendations should consider the impact of pharmaceutical costs on Connecticut's healthcare system and the final impact such costs have on the consumer. To the extent possible it is recommended that any initiatives to lower costs, when appropriate, include an ongoing comprehensive education requirement incorporating the elements developed by the Healthcare Education Work Group.

Please note that in certain cases there may be value in requiring through legislation activities to be implemented which are within existing administrative authority. Legislation helps to identify legislative priorities and ensures that activities will continue across administrations.

Priority Recommendations

1) <u>Legislative Priorities</u>

- a) Identify and investigate potential abuse in the pricing of both brand and generic drugs by creating a new Drug Review Board (DRB) and empowering it to investigate drug pricing decisions by manufacturers, both launch prices and price increases, with the purpose of determining if the prices are sufficiently unjustified in comparison to market norms and/or clinical value that it puts patient health at risk and therefore warrants referral to the Attorney General to pursue the manufacturer for a potential unfair trade practice violation.
 - i) The DRB should consist of clinicians, health economists and include consumer representation. Legislation creating the DRB should consider developing conflict-ofinterest rules for the membership similar to those employed by the Federal Drug Administration to avoid conflicts of interest.
 - ii) The DRB will require referrals of drugs for further investigation and access to information in order to perform its duties. In order to ensure the DRB has access to needed information CID should share state rate filing information related to pharmaceutical with the DRB, including the new filing requirements proposed in this document should they be adopted. In addition, the state Medicaid program and the State Employee Health Plan should be allowed to refer drugs to the DRB for review. The DRB should also be provided access to de-identified claims data through the

APCD to perform its analysis. Upon opening up an official investigation on a specific drug, the DRB should be given statutory authority to request additional information from manufacturers to inform its review process. Any information provided to the DRB from manufacturers should be expressly exempt from FOIA.

- iii) In order to enforce the findings of the DRB legislative action should be taken to change Connecticut price gouging statues to include unjustified pharmaceutical prices or price increases as determined by the DRB, thereby giving the Attorney General the authority to pursue price unfair trade practice or price gouging cases against pharmaceutical manufacturers (both generic and brand) whom the DRB finds to have imposed unjustified price increases or launch prices.
- b) Require manufacturers, PBMs & health insurers to disclose to the Office of State Ethics the funding they provide to nonprofit patient advocacy groups, and post such information on a publicly available website.
 - i) A recent <u>study</u> in the New England Journal of Medicine found that more than 80% of patient advocacy groups accept money from drug manufacturers. Meanwhile there are limited requirements for such groups to disclose their funding sources. In many cases disease specific advocacy groups receive large donations from drug manufacturers with patented drugs that treat the disease for which the group advocates for. At the same time many of these groups employ registered lobbyists to advocate for their interests and those they represent. Like other actors in the medical industry, including device makers, doctors and other providers, patient advocacy groups should be required to consistently report their financial donations so that the public and the law makers they are lobbying are fully aware of any potential conflicts of interest that may exist.
 - ii) It is recommended that the reporting requirement be put on the manufacturer, PBM or health insurer, large sophisticated organizations, in order to avoid placing the burden on smaller non-profit advocacy groups.
 - iii) Finally, it is recommended that manufacturers, PBMs & health plans only be required to report donations to the Office of State Ethics made to advocacy groups that are registered lobbyists in the state of Connecticut.

- c) Require that PBMs doing business with clients in CT allow and cooperate with audits when requested by such clients and establish minimum standards regarding the conduct of such audits.
 - i) PBMs generate the majority of their revenue from their contracting with pharmacies and manufacturers. The contractual relationships with these entities is not publicly disclosed, or even disclosed to the plan sponsors with whom they contract to manage pharmacy benefits. Plan sponsors sign good faith contractual agreements with PBMs that guarantee certain pricing on various types of prescription drugs. The contracts also dictate a certain percentage of rebates to flow back to the plan. Since the PBMs contractual relationships are kept secret, the only ability a plan sponsor has to ensure the PBM is meeting the contractual terms is to engage in an audit of the PBMs practices. However, not all PBM contracts allow for audits, and some that do put strict limitations on the terms and conditions of the audit. In order to ensure that all plan sponsors have the ability to review the performance of the PBM with whom they contract certain minimum audit standards should be required within every contract signed in Connecticut between a plan sponsor and PBM. Such requirements should include:
 - (1) That PBMs which have any contractual agreement(s) with any clients in Connecticut must allow and cooperate with audits, no more frequently than annually, when requested by its insurer, employer or multiemployer, or other client.
 - (2) For such audits, the PBM clients shall have sole authority to select and hire the qualified auditor of their choosing and shall be solely responsible for such auditor's costs.
 - (3) Compliance with such audits shall include electronic transmittal of required data, contracts and other information, as appropriate and requested by such auditor. Any such transmittal of data and/or other information shall, at all times, be protected using encryption and other standard security measures, by all parties. Such transmittal of data and other information should be subject to and covered by appropriate non-disclosure agreements
 - (4) The PBM shall provide all requested data and other information within 30 calendar days of receipt of auditor's request.

- (5) Upon receipt of the audit findings, PBM has 30 calendar days to contest any such findings and another 30 calendar days to reconcile and resolve any outstanding issues regarding such audit findings with the PBM client.
- d) Require that all prices negotiated between PBMs, manufacturers and payers pass through to the consumer at point-of-sale by requiring consumer coinsurance and deductibles be based on an estimate of the negotiated price (net price after rebate) of the drug rather than the list price or price prior to rebate.
 - i) Currently, most co-insurance and deductible payments at the pharmacy counter are calculated using the list price of a drug. This means that consumers must pay a percentage of (coinsurance) or the entirety of (up to deductible cap) the list price of a drug even though their health plan will pay significantly less for the drug after a rebate from the manufacturer. The phenomena of calculating coinsurance and deductible payments off of the list price is unique to prescription drugs. For all other health plan covered medical services coinsurance and deductibles are calculated off of the health plan's negotiated rate, rather than the hospital charge master for example. The difference in immediate out of pocket costs to the consumer can be significant.
 - ii) Studies have shown that even small changes in member cost share for pharmaceuticals can have significant impacts on medication adherence. Allowing consumers to directly benefit from manufacturer rebates on the drugs they need will improve medication adherence by lowering the immediate out of pocket costs for the medications. Greater medication adherence can improve health outcomes and lower total medical costs.
 - iii) Opponents of this recommendation will point out that any cost savings realized by the consumer in terms of lower out of pocket at the pharmacy counter will be offset by increases in premium share. This is not disputed, however reducing the out of pocket cost at the pharmacy counter has the additional benefit of potentially improving medication adherence and thereby lowering medical costs for some chronic disease patients.

2) Administrative Priorities

- a) Require insurers to report more granular information to the Connecticut Insurance Department (CID) on the impact of prescription drug price increases on premiums in their annual rate filing and compile such information into a public report.
 - i) Currently, pharmacy spend accounts for 22-23% of fully insured premiums in the state of Connecticut. The contribution of pharmacy drugs to overall premium costs has been increasing in recent years as pharmacy drug cost increases have outstripped the increases in medical costs. However, the CID and policy makers do not know which drugs or drug classes are contributing most to the overall increase in pharmacy costs for the health plans regulated by the state. Plans only report the total pharmacy spend and an aggregate rebate amount, which offsets aggregate spending in plan rate filings.
 - ii) CID should require more detailed reporting from the insurers, at least commensurate with the requirements included in SB 17 in California. Carriers operating in the California market, which includes many of Connecticut's carriers, will now be required to report:
 - (1) For all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use, all of the following shall be reported:
 - (a) The 25 most frequently prescribed drugs.
 - (b) The 25 costliest drugs by total annual plan spending.
 - (c) The 25 drugs with the highest year-over-year increase in total annual plan spending.
 - iii) For each category plans should be required to report both gross and net spending to account for the impact of rebates. Such reporting would provide CID with a clear view of which drugs are driving pharmacy cost increases in Connecticut, and thus contributing to increasing premiums for health care consumers.
 - iv) As in California CID should compile the information provided into a report for the public and legislators that "demonstrates the overall impact on health care premiums". It is recommended that information in the report be aggregated so as to not reveal information that is specific to an individual health carrier or otherwise divulge proprietary pricing information. Such company specific proprietary information may be protected by federal law and provides limited value to consumers or health policy makers.

- v) Finally, California SB 17 requires manufacturers to report at least 60 days in advance to health insurers and pharmacy benefit managers of a planned price increase that exceeds certain thresholds. The CID should require any such information reported to health carriers regulated in Connecticut be reported to the CID and such information should be included in the CID report described in the above paragraph. Any such information included in the public report should be aggregated or otherwise de-identified so as to protect manufacturer proprietary information.
- b) The SIM Quality Council should seek to add quality measures to the core measure set related to: medication adherence, assistance and monitoring; and communication with patients about drug prices, barriers, the clinical value of each prescription, patient priority setting and alternatives.
 - i) A study published last year found that only 30% of patient/provider conversations about three medical conditions with potentially high out-of-pocket costs (breast cancer, depression and rheumatoid arthritis) involved the costs of medications. Physicians rate the cost of medications as the least important factor to discuss with patients – effectiveness and intended impact is more salient and 35% of consumers taking drugs say a provider has never reviewed their medicines to see if they could stop any (Consumer Reports). A Consumer Reports survey found that a large and increasing number of Americans are not filling prescriptions, skipping doses or cutting pills in half (without talking with their provider). When these drug cost conversations with consumers do occur, consumers are often able to provide important help in finding alternatives, setting priorities, and identifying resources to pay for medications. To improve the number and quality of conversations with patients about medication costs and priority setting, these communications should be formalized, and included in quality measures for new payment models. While nationally recognized measures are developed, health systems, insurers and payers can use patient surveys and other methods to track these communications. (Patient surveys are critical – if patients do not remember or find the conversations useful, they are not effective). When considering these new quality measures, the SIM Quality Council should explore what kind of mechanism should be employed in order to most effectively formalize these conversations, including alternatives that do not directly fall under the responsibility of primary care providers.
 - ii) It is recommended that pharmacists be added to patient care teams to assist in fulfilling the above requirements

- c) SIM, through practice transformation grants and the learning collaborative, should identify and promote opportunities to incorporate decision aides that utilize comparative effectiveness research, into provider EHR systems to assist doctors in making prescribing decision.
 - i) Comparative effectiveness research compares the relative effectiveness of various drugs in a therapeutic class in treating certain conditions. Utilizing comparative effectiveness research in decision aides built into a physician practice's EHR and incorporated into the typical office visit workflow would result in improved prescribing patterns, better outcomes and lower costs.

Other Recommendations by Work Groups Considered by the Cabinet

3) Other Legislative Recommendations

- a) Require on-line availability of price data for drugs covered by co-insurance.
 - i) Currently, regulated health insurance carriers in Connecticut must provide access to online tools that calculate member cost share for various medical procedures. The requirement does not extend to the pharmacy benefit. CID has indicated that it does not believe that it has the authority to require on-line availability of-out-of-pocket pharmacy costs of price data for drugs covered by insurance, thus an expansion of the original law to include pharmaceuticals is required.
 - ii) This information should be available on the insurer's website during open enrollment so consumers can make informed choices.
- b) Require PBMs to exercise "fiduciary responsibility" (i.e., they must act in their client's best interest) when contracting in the state of Connecticut.
 - i) The financial interests of PBMs and the plan sponsors they serve are not always aligned. As a result, in certain instances PBMs may make formulary decisions or pharmacy network decisions that are not in the financial best interest of the plan sponsor. Requiring PBMs to accept a fiduciary responsibility on behalf of the plan sponsor would require the PBM to always act in the best interest of the plan sponsor, thereby avoiding scenarios in which the PBM, acting in its own best interest, may make decisions that otherwise drive up costs for the plan sponsor.
 - ii) The CT Department of Consumer Protection should be considered as the potential agency with enforcement authority.

- c) Explore the feasibility of creating a state administered revolving loan program that allows patients that are challenged by the structure of high deductible plans or with significant co-insurance responsibilities the opportunity to amortize the upfront costs incurred at the start of each plan year.
 - i) Currently certain patients with disease states that require high cost maintenance medications are certain to quickly hit their deductible and or out pocket maximum early in the plan year, creating a significant short term expense. Not all consumers have good options to spread out this cost over the course of the year creating significant financial hardship and sometimes challenging medication adherence. Such a program could provide an avenue for such patients to better manage these costs.
- d) Require facilities and physician offices to publicly post in the office or facility, already publicly available information about gifts and monetary compensation accepted from drug manufacturers.
 - Consumers are unaware of financial relationships/conflicts of interest that healthcare providers have with pharmaceutical companies which potentially influence prescribing behaviors and increase costs to both the consumer and the system.
 - ii) Transparency and access to full information concerning conflicts of interest at the point of service should better enable consumers to question providers about prescribing decisions upfront. It is not reasonable to expect that patients will navigate to the information publically available on the internet at the time of service, when the prescription is written. However, if the information is prominently posted in the waiting or exam rooms, patients will have a more informed opportunity for inquiry and potentially be able to gain comfort that the prescribing decision was made without conflict. And further, it should be noted that such a standard already exists for the publication of medical research where conflicts are required to be disclosed and readers are not required to independently investigate researcher conflicts. Accordingly, there appears to be a double standard when comparing provider to provider disclosure of conflicts to provider to consumer/patient disclosure.
 - iii) Under the ACA drug manufacturers are required to report certain gifts and monetary compensation they give to health care providers. The information is publicly posted at https://www.cms.gov/openpayments/ Requiring such information, as is already

available on the government website, be posted in a conspicuous area within a providers office would increase the number of patients who are aware of potential conflicts of interest, allowing them to discuss any potential issues with their provider and perhaps reducing the extent to which providers are willing to accept gifts in the process.

- e) Set co-payment and co-insurance maximums per month of \$250 for most plans (\$500 for bronze ACA plans), per 30 supply.
 - i) Consider modeling legislation on a California law that set the limits above. California conducted an actuarial analysis finding that there would not be an increase in premiums if monthly copay or co-insurance caps were set at these levels. The California law applied differently to high deductible health plans, but limited annual deductibles for outpatient prescriptions to twice the copay/ co-insurance limits. CID believes there may initially be an increase to premiums. The cost savings may come over time as individuals might be more apt to adhere to their medication regiment if there was a monthly deductible versus annual. See OLR Research Report, State Laws Limiting Prescription Drug Cost Sharing.
- f) Limit manufacturer coupons for drugs to only those situations in which a lower cost brand name or generic drug is not available in the same therapeutic class and develop a robust exemption process for any prohibition.
 - i) Manufacturer coupons can be used to undermine formulary strategies designed to lower costs or prefer medications that provide the most value. In certain instances, manufacturers use coupons to reduce or eliminate patient cost shares, in certain instances making a non-preferred drug lower cost to the patient than either a generic or preferred brand alternative in the same therapeutic class. The drug manufacturer benefits from this arrangement by increasing its market share. Often the manufacturer reimbursement for their drugs when in a non-preferred status is greater than the manufacture might receive when preferred, since the coupon strategy does not require the manufacturer to provide the PBM significant price concessions in the form of rebates to be considered preferred on the PBMs formulary. Thus, payers insurers and self-insured employers incur increased pharmacy costs as a result of manufacturer coupon strategies. For patients, some may benefit in the short-term through lower copays and coinsurance offset by the manufacturer coupon, but everyone pays more over the long-term due to increased premiums to cover the costs of the higher cost clinically equivalent drugs.

- ii) California recently passed a law to limit manufacturer coupons to products for which there is no lower cost clinically equivalent alternative, instances in which a patient may benefit, without adding extra costs to the overall system. The issue of coupons is a challenging one, in that they can help to reduce out of pocket costs for some patients. Allowing coupons under certain circumstances may be appropriate, including when no clinically equivalent lower cost alternative exists or in plan designs that base coinsurance on the cost over and above a reference price. In such scenarios the use of a coupon would benefit the patient without increasing overall health care costs. When no lower cost clinically equivalent exists the coupon merely lowers the patients out of pocket costs without moving market share to a higher cost drug. When a plan uses reference pricing the plan is only subject to the costs of any drug up the cost it would pay for the lower cost clinically equivalent alternative, thus while the coupon may shift market share it does so in a way that does not drive up premium costs.
- iii) In certain instances, a patient may require the brand drug over the generic or the non-preferred brand name drug over the preferred for medical reasons. The intent of this proposal is not to limit access to coupons that will lower out of pocket costs to such patients, therefore any such prohibition should allow an exemption process based upon medical necessity.
- iv) At a minimum significant effort should be made to educate consumers about the different types of patient assistance and coupon programs that may help them afford their medications and the long-term impact on prescription drug premiums.

g) Prohibit retroactive pharmacy fees to ensure transparency in the financial relationship between PBMs and pharmacies.

- Prevent insurance companies and PBMs from applying Direct and Immediate
 Remuneration (DIR) practices (typically found in Part D plans) to commercial plans
- ii) Example from Louisiana: A health insurance issuer or a pharmacy benefit manager may not directly or indirectly charge or hold a pharmacist or pharmacy responsible for any fee related to a claim:
 - (1) That is not apparent at the time of claim processing;
 - (2) That is not reported on the remittance advice of an adjudicated claim, after the initial claim is adjudicated.

- iii) Example from pending federal legislation: Each contract entered into with a PBM shall provide that after the date of receipt of a clean claim submitted by a pharmacy, the PBM may not retroactively reduce payment on such claims directly or indirectly through aggregated effective rate or otherwise except in the case such claims found to not be a clean claim during the course of a routine audit as permitted pursuant to a written agreement between the plan sponsor and such pharmacy.
- iv) Define what a "clean claim" is (those without any defect, impropriety or fraud).
- h) The contracts that PBMs have with pharmacies in the state of Connecticut shall not reimburse the pharmacy less than the reasonable cost at which the pharmacy purchases the drug.
 - i) In order to ensure reasonable reimbursement, the state should adopt the following provisions:
 - (1) Require PBMs to update MAC lists every 7 days and make the lists available in a searchable spreadsheet format.
 - (2) In order for a drug to be included on the MAC list they must meet the following criteria:
 - (a) Drug must have at least three nationally available, therapeutically equivalent multiple source generic drugs.
 - (b) The products must be listed as therapeutically and pharmaceutically equivalent or "A" or "AB" rated in the "Orange Book."
 - (c) Must be available for purchase by all pharmacies in the state from a national or regional wholesaler
 - (d) Maintain a procedure to eliminate products from MAC lists if they don't satisfy requirements for inclusion.
 - ii) PBMs should be required to establish an appeal process, through which pharmacies and appeal reimbursement decisions.
 - (1) If the appeal is denied, the PBM must provide the reason for the denial and identify where the drug can be purchased at a price at or below the MAC price.

- (2) If the appeal is upheld, the PBM must adjust the MAC list and make the adjustment retroactive to the date of initial adjudication. The adjustment must be made for all pharmacies.
- iii) In order to enforce the provisions above legislation should:
 - (1) Specify which agency will have enforcement authority; and
 - (2) Establish a private right of action permitting pharmacies to sue a PBM that violates these provisions.
- Explore the option of expanding access to the state employee pharmacy contract terms, which is now available to non-state public employers, to private sector entities.
 - i) Currently, such a proposal would only allow other payers better PBM contract terms than they could get on their own but would not change the overall dynamics of the market. However, should the state plan move more toward a transparent PBM contract focused on value and total cost of care the state plan could provide a real alternative to the predominant PBM structure which is ripe with perverse incentives. Expanding the availability of the state's contract terms with its PBM vendor beyond the non-state public employers the state currently allows would require forgoing the state's government exemption from federal ERISA rules and regulations.

2) Other Administrative Recommendations

- i) Create a mechanism, (e.g. statewide board or collaborative) to create, promote and monitor consumer education efforts across the health care continuum. Such an entity should include providers from all levels of care, consumers plan and practice administrators and related government entities. The board or collaborative should be charged with:
 - i) Holding all sources accountable for consistency and continuity of education messaging.
 - ii) Creating a process whereby all stakeholders participate in an independent review process that safeguards consistency and continuity consumer education messages.
 - (1) Policies and decisions from the review process must be in writing and publicly available.

- iii) Integrating all treatment options, including non-pharmacy options are included in communications.
- iv) Ensuring that communications with consumers and prescribers balance the use of lifestyle change and wellness interventions with pharmaceutical use.
- v) Promoting patient-centered engagement and shared decision making in communications about treatment options. (DPH, OSC, CID, DCP, OHA, Medicaid/DSS, SIM, OHS).
- j) Promote the availability of existing resources that allow consumers to compare the cash price of prescription across pharmacies to consumers so they can reduce their personal expenses for prescription drugs.
 - i) Currently, there are several tools that assist consumers in finding the lowest cost pharmacy to fill their prescription. Such tools can be very useful because there is significant variation in sticker prices of pharmaceuticals across pharmacies in the state.
 - ii) Such information is most useful to those in their deductible or those who do not have prescription drug coverage.
- k) Evaluate the potential benefits of various types of value based contracts for supplemental rebates, including the results in other states pursuing such contracts at this time, and report back findings to the Health Care Cabinet.
 - i) Several state Medicaid programs are actively pursuing value based contracts. The overall impact of such contracts is uncertain as they have had mixed results in Europe and are two new in the US to draw any conclusions. Medicaid is looking to gather additional information about the impact of such contracts in other states to determine if such an approach is prudent for them to undertake.
- Create a work group, inclusive of all stakeholders including consumer representation, to evaluate the potential risks and benefits of adding exclusions or more onerous prior authorizations to the Medicaid formulary in order to drive toward value based pricing
 - i) Under current federal rules Medicaid has to cover drugs where there is a <u>Federal</u> Rebate in place. Medicaid also negotiates supplemental rebates and may add prior

- authorizations for drugs reviewed by the P&T committee where there is no supplemental rebate.
- ii) NY and MA are considering options to challenge this provision to lower total costs. There are concerns about high cost rare disease drugs being targets for exclusions, but can the option under consideration be an avenue to reduce wasteful spending on low value high cost products (e.g. Duexis)?
- iii) Any evaluation of adding exclusions or additional prior authorizations should include a rigorous examination of whether the proposed change would result in discrimination to individuals with high-cost chronic or rare diseases.
- iv) The work group could evaluate both the potential to reduce overall costs and the risks to vulnerable populations. In certain instances, the value of excluding or putting tight PAs on certain drugs may outweigh the risks. For instance, the state plan just instituted a significant PA for products made by Horizon pharmaceuticals. These products are combinations of long available generic and over the counter products. While the combination product does add some level of convenience it is priced thousands of dollars more. Such high prices for such low cost drugs is clearly wasteful, limiting access to such combination drugs to only those who really need it saves the system money without negatively impacting patients. Such scenarios must be considered and evaluated by such a work group to determine a) if there is value in adding exclusions or tighter PAs and b) if so what are the criteria under which such options would be evaluated to ensure patients retain access to needed medications.
- v) In order to ensure adequate consumer representation, the Consumer Advisory Board (CAB) should be consulted when appointing consumer stakeholders to the workgroup.
- m) Ensure the state employee plan maximizes the value of its pharmacy expenditures by improving outcomes and reducing overall medical costs by:
 - (1) Make capacity and engagement in value based contracting a consideration in selecting a PBM vendor
 - (2) Require PBM to utilize independent analysis of the therapeutic value of drugs, including their comparative effectiveness and cost-effectiveness, to build a value based formulary
 - (3) Explore opportunities for direct engagement with manufacturers

- ii) The state plan needs to move from evaluations of PBM vendors based specifically on potential pharmacy savings primarily rebate savings and pharmacy network discounts to one that is focused on reducing overall medical costs and improving patient outcomes. Moving in this direction may require engaging in a transparent PBM relationship where the state pays the PBM an administrative fee for services, and requiring that all manufacturer payments pass through to the plan.
 - (1) The traditional PBM structure is rife with perverse incentives which can increase rather than limit total drug costs. For instance, because a major revenue source for the PBM is the rebate from the manufacturer, the PBM has incentive to prefer the drug with the highest rebate, not necessarily the one with the lowest cost. Likewise, a drug's clinical value may be secondary to the rebate it provides the PBM. Finally, to the extent the PBM is seeking to lower overall costs it only has incentive to show contained pharmacy costs for its clients. Since pharmacy costs are often siloed from medical costs, the formulary may not reflect the clinical value of medications.
 - (2) The state plan, with its large size should seek to move toward a PBM relationship in which the interests of the PBM vendor are aligned with the interest of the state and participants of the state employee health plan. This will require the movement to a transparent PBM structure that builds its formulary based upon the relationship between a drugs clinical value and price, not its rebate.
- n) Over the long-term determine if Medicaid's capacity and expertise in formulary development and rebate contracting could be utilized by the state plan
 - i) One avenue for ensuring the incentives of the PBM are aligned with the state plan is to utilize another state entity to perform core PBM functions. Medicaid performs many such functions for the Medicaid program, leaving open the question of whether the infrastructure could be utilized by the state plan as well. There are some clear challenges to the state plan utilizing Medicaid's infrastructure including the variance in available drug pricing from manufacturers between Medicaid and the commercial market, the differing populations served and the limit of the Medicaid pharmacy network to in-state pharmacies. To date several states have looked at options for combining the buying power of their state plan and their Medicaid program to lower costs and leverage better pricing, however there are not any examples of successful integration to date.
- o) The APCD should be utilized to illustrate trends in out-of-pocket costs, for use by the Office of Health Strategy and other state policy makers to inform future policy.

- p) The Office of Health Strategy should further research and refine the following recommendations:
 - Require benefit designs that separate and have much lower deductibles for prescription drugs than medical deductibles.
 - ii) Require benefit designs that separate & have a lower OOP maximum for prescription drugs vs. medical OOP max.
 - iii) Eliminate co-pays for asthma, high blood pressure, diabetes & high cholesterol medications, and consider also congestive heart failure and COPD.
- q) As part of its mandate to promote value based insurance design (VBID) the SIM VBID consortium should consider promoting formulary designs that focus on value by tying formulary placement to value, not rebate size:
 - i) Using an independent assessment of value, purchasers can have a formulary that assigns tier and cost-sharing by how close the drug price is to the benefit it brings to patients (value-based price)
 - ii) Any process to determine value-based benchmarks should be transparent.
 - iii) Drugs priced at or below the value-based price benchmark received preferred tiering (tier 1 or 2), with little or no cost-sharing for patients (co-pay instead of co-insurance).
 - iv) Drugs priced above the benchmark can be treated one of two ways: 1) they are excluded or 2) the purchaser reimburses up to the value-based price.
 - v) Right now, formulary status (whether a drug is tier, 1, 2, 3 or 4) is often a result of the size of rebate offered by the manufacturer to the payer, not on whether the price is aligned with the long-term value the drug brings to patients. For example, a drug that has average effectiveness for rheumatoid arthritis, but that is used for many different indications, may enjoy tier 1 status for rheumatoid arthritis, because the manufacturer gives the payer a large rebate to place it on the preferred tier. In this model, a more effective, higher-value drug is placed in a less desirable tier, and that patient often has to pay more for it out of pocket. A shift to a value-based formulary means that the tier placement is tied to the drug's effectiveness and value, not the size of the rebate. Using independently produced calculations of

value-based prices, the state could enact a drug formulary that rewards drugs for being priced fairly (tier 1 or 2, with minimal or no cost-sharing for patients), and assigns drugs to higher tiers when manufacturers choose to price the drug far above its value to patients. When the price is out of line with value, the drug could be excluded (with a robust and fair exceptions process), or the drug could be reimbursed up to the value-based price (with the difference the responsibility of the patient, with perhaps support from the manufacturers to afford the cost difference). This approach has the potential to save the state and patients money.

- r) The Office of Health Strategy should review the potential for wholesale importation from Canada; to determine, through its own analysis with input from all stakeholders, whether such efforts would be viable in Connecticut and if they would best serve the public interest and report such findings to the Health Care Cabinet.
 - i) The US pays about twice the price for drugs as Canada, while the quality and safety of drugs in Canada is equal to the US. For many years, individual Americans have crossed the border into Canada to access more affordable medications. A state wholesale drug importation program could share those benefits with all state residents and payers. Such a program would require federal approval based on whether it is safe and saves money for consumers. A recent Supreme Court decision has removed a critical legal hurdle to importation of drugs. In *Impression Products, Inc. v Lexmark International Inc.,* the Supreme Court ruled that patent law cannot be used to prevent the resale of products back into the United States.
- s) The Office of Health Strategy should review the potential for a public utility model for drug price oversight, to determine, through its own analysis with input from all stakeholders, whether such efforts would be viable in Connecticut and if they would best serve the public interest and report such findings to the Health Care Cabinet.
 - i) Connecticut has a long history of regulating the price of essential goods and services critical to the health and wellbeing of state residents such as electricity and gas. States have always regulated the price of health insurance premiums, often lowering rate requests from insurers. The pharmaceutical market has become less and less competitive driving up prices. This trend goes beyond drugs that have been granted market exclusivity by the federal government to include even generics which have experienced massive price increases. The state could create an independent, strictly non-conflicted price review board that follows a transparent, evidence-based process to review and set enforceable price limits. There are many possible structures and enforcement mechanisms. As for other review boards and insurance

price regulation, the process could be funded through assessments on the industry, causing no burden on the state General Fund.

