RECOMMENDATIONS ON PHARMACEUTICAL COST CONTAINMENT STRATEGIES

Health Care Cabinet

February 15, 2018
Welcome from Lt. Governor Nancy Wyman

As Chair of the Health Care Cabinet, I’m pleased to share the Cabinet’s final report, “Recommendations on Pharmaceutical Cost Containment Strategies.” This report follows the Cabinet’s January 2017 report on Cost Containment Strategies and represents a year-long effort to study the impact of rising pharmaceutical costs on Connecticut residents, business, and government. The Cabinet recognizes the complexity of this issue and thanks its work groups, stakeholders, and the pharmaceutical industry for their effort to develop recommendations. This report represents the consensus of the Cabinet for consideration by the General Assembly. We hope it will inform your decision-making on cost containment and access to prescription drugs.

Nancy Wyman
Lieutenant Governor
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Executive Summary

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 report, 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. A summary of that work is included as Appendix A. In the second half of the year the Cabinet created working groups to develop more detailed recommendations related to pharmaceutical costs.

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. After a month long public comment period and public discussion of those comments, the Cabinet reduced the number of its priority recommendations guided by the Cabinet principles below. This report represents the best efforts of the Cabinet. It emphasizes the recommendations that the Cabinet determined to be of the highest priority and includes in an appendix other recommendations that were considered. The Cabinet and its work groups deliberated in an attempt to balance the interests of all stakeholders on this complicated issue.

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

RECOMMENDATIONS

1. 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.

2. Require manufacturers, Pharmaceutical Benefit Managers (PBMs) & health insurers to disclose to the Office of State Ethics the funding they provide to nonprofit advocacy groups, and post such information on a publicly available website.

3. 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.

4. 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.

Administrative Recommendations

1. 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 beginning in 2019 and compile such information into a public report.

2. The State Innovation Model (SIM) Quality Council should examine the potential value of diversifying the current medication counseling question in CAHPS to better reflect barriers to medication adherence, need for assistance and medication monitoring, and should explore tying CAHPS results to value based payment. The Quality Council should also monitor the availability of NQF endorsed quality measures as part of its annual review to determine if meaningful measures for medication adherence, assistance and monitoring become available.

3. The SIM Practice Transformation Task Force and the Education Work Group of the Cabinet should examine how providers can better communicate with patients about drug prices, barriers, the clinical value of each prescription, patient priority setting and alternatives.

4. 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 decisions.

A total of 37 public comments were received on the draft report issued on January 2, 2018. The Cabinet considered all public comment in formulation this final report. (The Cabinet includes as an addendum all recommendations considered, a narrative on the table-setting work the
Cabinet undertook to develop recommendations and hyperlinks to all comments received on the report.)
Recommendations for Pharmaceutical Cost Containment Strategies

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 report, 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:

1. 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. The workgroups considered background information on the rate of growth of pharmaceutical expenditures, the importance of the pharmaceutical industry to Connecticut and its contributions to improving health of Connecticut residents, activities in other states, expert input and public comment at multiple work group meetings.

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

After a month long public comment period and public discussion of those comments, the Cabinet reduced the number of its priority recommendations guided by the Cabinet principles below. This report represents the best efforts of the Cabinet to balance the interests of all stakeholders while addressing concerns of the effects of rising costs on Connecticut residents, employers and state government. It emphasizes the recommendations that the Cabinet determined to be of the highest priority and includes in an appendix other recommendations that were considered and public comment received. (See Appendix B.)

Several additional recommendations were put forth through public comment and are available online through the consolidated comments document.

**Cabinet Work Guided by Principles**

The Cabinet makes the following recommendations for legislative and administrative action adhering to the above principles.

**Health Care Cabinet Operating Principles**

*(Approved June 14, 2016)*

1. **Commitment to Impact**: Contribute to the improved physical, behavioral, and oral health of all Connecticut residents as seen in the following:
   a. The number of individuals and/or constituencies affected
   b. The depth and/or intensity of the problem
   c. Reduction of barriers and burdens for those most vulnerable
   d. The time frame in which change can occur
   e. The cost effectiveness of health and health care purchasing that promotes value and optimal health outcomes.
   f. A health insurance marketplace that provides consumers a competitive choice of affordable and quality options.

2. **Equity in health care delivery and access**: Recommendations incorporate the goal of reducing disparities based on race, ethnicity, gender, and sexual orientation.

3. **Leverage**: Recommendations must:
   a. Make the best use of past and current knowledge and expertise.

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b. Maximize the opportunities provided through initiatives from the public and private sector.
c. Be informed by data and evidence-based practice and research.
d. Be sustainable.

4. Accountability and Transparency: Be fully accountable to the public in a transparent process that meets the objectives of Public Act 11-58.
   a. Identify and measure outcomes that demonstrate meaningful results
   b. Maintain consumer-driven goals throughout the process

5. Inclusion: Ensure that there are meaningful opportunities to obtain a broad cross-section of views from all stakeholders, including consumers, communities, small business, payers, providers and government.

6. Action: All recommendations must take into account implementation and position of Connecticut to seize opportunities.

A total of 37 public comments were received on the draft report issued on January 2, 2018. The Cabinet considered all public comment in formulation this final report. (The Cabinet includes as an addendum all recommendations considered and a narrative on the table-setting work the Cabinet undertook to develop recommendations.)

Summary of Selected Pharmaceutical Cost Provisions from Other States

In developing recommendations to contain pharmaceutical costs, four workgroups were assembled from Cabinet membership. The workgroups heard from experts to assist the groups in developing 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**

1. **Transparency Measures**

   **California**

   a. S.B. 17 (law passed)
      i. 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)
      i. 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 de-identified)

viii. Litigation: Yes (PhRMA & Biotech)

**Pennsylvania**

c. **H.B. 1464 (did not pass)**
   i. 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**

iii. 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)
   i. Section 802 – “Price gouging” prohibited
   ii. Section 801 – “Price gouging” defined as “unconscionable price increase”
iii. Section 801 -- “Unconscionable price increase” defined as “(1) IS EXCESSIVE AND NOT JUSTIFIED BY THE COST OF PRODUCING THE DRUG OR THE COST OF APPROPRIATE EXPANSION OF ACCESS TO THE DRUG TO PROMOTE PUBLIC HEALTH; AND (2) RESULTS IN CONSUMERS FOR WHOM THE DRUG HAS BEEN PRESCRIBED HAVING NO MEANINGFUL CHOICE ABOUT WHETHER TO PURCHASE THE DRUG AT AN EXCESSIVE PRICE BECAUSE OF: (I) THE IMPORTANCE OF THE DRUG TO THEIR HEALTH; AND (II) INSUFFICIENT COMPETITION IN THE MARKET FOR THE DRUG.”

iv. Section 803 - 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 AND if a 30-day supply or full course of treatment would cost more than $80

v. Information public: No

vi. Effective date: Oct. 1, 2017

vii. 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


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
   i. 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/


**White Papers and Other Resources**


IX.  *States and the Rising Cost of Pharmaceuticals: A Call to Action*, NASHP’s Pharmacy Cost Work Group (October 2016)

**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 Cabinet formed draft and final recommendations 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) Legislative Priorities

1. 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 adequate consumer representation. Legislation creating the DRB should consider developing conflict-of-interest 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.
2. **Require manufacturers, PBMs & health insurers to disclose to the Office of State Ethics the funding they provide to nonprofit advocacy groups, and post such information on a publicly available website.**

   i) A recent study 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 non-profit advocacy groups that are registered lobbyists in the state of Connecticut.

3. **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.

4. 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) It is important to note, any out of pocket cost savings realized by the consumer at the point of purchase at the pharmacy counter under this recommendation will be offset by increases in premium share. Currently prescription drug rebates negotiated by health carriers are reflected in lower overall premiums to consumers and reflect a reduction in pharmacy claims. This recommendation would remove those pharmacy rebates from health carriers’ premium rate filings, resulting in no reduction to pharmacy claims, and an increase in existing overall premiums to consumers of 3% to 4%.

iii) However, reducing the out of pocket cost at the pharmacy counter for a consumer provides the benefit of potentially improving medication adherence and thereby lowering medical costs for some chronic disease patients. 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 may 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.

2) **Administrative Priorities**

1. **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

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3 For those carriers that negotiate their own pharmacy rebates the increase to premiums would be higher than the range provided.
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.
2. The State Innovation Model (SIM) Quality Council should examine the potential value of diversifying the current medication counseling question in CAHPS to better reflect barriers to medication adherence, need for assistance and medication monitoring. The Quality Council should also monitor the availability of NQF endorsed quality measures as part of its annual review to determine if meaningful measures for medication adherence, assistance and monitoring become available.

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 to the extent such quality measures are available. 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 Practice Transformation Task Force 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

3. SIM, through practice transformation grants and the learning collaborative, should identify and promote opportunities to incorporate decision aids 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.

The Cabinet wishes to thank all who participated in the process of developing these recommendations, including work group members, stakeholders who participated throughout the process, public commenters and experts who provided much of their time to this effort.
Appendix A

Historical Narrative on Cabinet Pharmaceutical Strategies Work

Background on Prescription Drug Costs Nationally and in CT

Healthcare expenditures have grown as a percentage of the overall economy, from 17.4% in 2014 to 17.8% in 2015. 4

In 2015, national health data shows that prescription drugs accounted for 10% of all healthcare spending.5 According to CMS, “spending on prescription drugs outpaced all other services in 2015. The strong spending growth for prescription drugs is attributed to the increased spending on new medicines, price growth for existing brand name drugs, increased spending on generics, and fewer expensive blockbuster drugs going off-patent.”6

At the same time, total out of pocket expenditures grew by 2.6%.7 Eighty-four percent of “specialty drugs” are subject to co-insurance on silver exchange plans in 2017.8 “Health spending by households grew at a rate of 4.7 percent, which was an acceleration from 2.6 percent in 2014. Household spending accounted for 28 percent of health care spending in 2015, unchanged from the year before. The faster growth in spending by households was driven largely by households’ contributions to employer-sponsored private insurance premiums....Health care spending financed by private businesses accelerated slightly, increasing 5.3 percent in 2015 compared to 4.7 percent growth in 2014.”9

In CT, employers identified health costs as a top concern, including specialty pharmacy drug spending.10 According to State Comptroller Kevin Lembo, who administers the state employee and retiree health plan, including pharmacy benefits for over 200,000 people, “even as overall drug utilization was down about 1.3 percent in Fiscal Year 16, and the overall medical cost trend was maintained at single-digit growth, the state pharmacy plan experienced a 15-

5 Ibid.
6 Ibid.
7 Ibid.
10 Cabinet Report at 10, citing Bailit Health’s interview with CBIA on April 20, 2016.
percent increase in costs over the prior year.”11 And in certain cases, costs for certain classes of drugs grew by significantly higher percentages—antidiabetic drug costs grew by 52% over the previous year.12 During the same time frame, the Department of Social Services (DSS) was able to lower its pharmaceutical expenditures by $55.8 million.13

Nationally, reports indicate that misuse of drugs costs up to $52.2B annually while overuse of antibiotics may cost $1.1B.14

**Cabinet Activity on Drug Spending**

The Cabinet began detailed discussions in 2017 centered on potential strategies to address growing pharmaceutical costs across all payers.15 The Cabinet elected to defer study of potential strategies to contain pharmaceutical spending until 2017 to allow sufficient time to develop meaningful recommendations.

In 2016, several Cabinet members volunteered to develop issues areas for exploration. The issue areas included:

- Better understand drug pricing
- Maximize state purchasing and regulatory powers to reduce pharmaceutical costs
- Optimize safe and effective use of medications

**A. Better Understanding Drug Pricing**

Cabinet volunteers concluded that a lack of understanding around manufacturing costs and pricing leave purchasers at a disadvantage and should drive the state to promote transparency on industry practices that impact pricing in several ways:

- Giving the Attorney General enhanced authority to investigate the industry, report on findings and hold a hearing to help educate the public

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12 Ibid.
15 Cabinet Report, Appendix F.
B. Maximizing State Purchasing and Regulatory Powers to Reduce Pharmaceutical Costs

Cabinet volunteers suggested that through the state’s payers, the state consider strategies addressing:

- Medicaid functioning as a contractor for pharmacy coverage
- Medicaid and the Comptroller’s office should consider the feasibility of jointly administering their prescription drug programs
- State agencies acting as contractors for coverage—contractual requirements and in-house expertise
- The state’s role as a bulk purchaser for certain drugs that have a public health benefit.
- The state’s role as a regulator.
- The state’s ability to tie its purchases to the lowest price paid for the same drug by the United States Department of Veterans Affairs, except as may be required by federal law.\(^\text{16}\)
- Creation of a public utility model to oversee drug prices.
- Passage of legislation requiring all providers prescribing or administering biologically based drugs to use biosimilar drugs, whenever available.

C. Strategies to optimize safe and effective use of medications

The Cabinet volunteer members made suggestions about areas to explore to ensure safe and effective use of medications, including:

- Expanding the role of community pharmacists in medical homes and primary care payment models.
- Working on standard discharge forms from skilled care that would allow for medication reconciliation with community providers.
- Restricting automatic refills and promoting the use of e-prescribing.

\(^\text{16}\) The requirement would also need to be implemented in a manner that does not jeopardize Medicaid’s best-price guarantee.
Ensuring the availability of clinical information across the provider spectrum to ensure proper medication reconciliation.

The Cabinet solicited multiple presentations, beginning in January 2017. The Cabinet heard from experts in academia and the industry on potential strategies Connecticut could pursue to control pharmaceutical costs. The strategies mirror some of those suggested by the Cabinet volunteer members in 2016. Presenters also offered additional strategies.

D. PRESENTERS

1. January 10, 2017

Presenters included:

- Ameet Sarpatwari, Ph.D. J.D., Harvard University
- Thomas Brownlie, Director, U.S. Policy, Global Policy Division, Pfizer
- Jennifer Bryant, Senior Vice President, Policy and Research PhRMA

In January, Ameet Sarpatwari, J.D., Ph.D. from Harvard, presented, “States and Rising Prescription Drug Costs: Origins and Prospects for Reform.” Joined in serial presentations by Tom Brownlie of Pfizer and Jennifer Bryant of PhRMA, Dr. Sarpatwari laid out the drivers behind increasing prescription drug costs and the ramifications of those costs upon consumers, employers and state budgets. Noting the rate of increase in drug costs, Dr. Sarpatwari pointed out that while more consumers have coverage for prescription drugs, consumers face higher out of pocket costs for medications than ever before, and some are not filling needed prescriptions because of out of pocket costs. He also noted that consumers adhere better to prescription drug regimens when they are prescribed more affordable, generic alternatives to name-brand drugs.

Dr. Sarpatwari noted that drug prices are higher because we allow companies to charge what the market will bear without allowing for a counterbalance. He stated that the availability of generic alternatives is the only competition that actually drives down prescription drug costs. He cited the restrictions on negotiation of drug prices for

17 Instructor in Medicine, Harvard Medical School, Assistant Director, Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital
18 We acknowledge the support of the Office of the State Comptroller’s assistance in requesting Dr. Sarpatwari’s appearance.
20 Ibid.
major payers in the United States, except for the Veterans Administration, recommending that states should drive reform.

Dr. Sarpatwari described the work of the National Academy of State Health Policy’s (NASHP’s) work group, a bipartisan work group that included Connecticut’s Comptroller. The ten possible state solutions developed by the work group include the following:

1. Leverage transparency laws to create accountability
2. Create a public utility model for in-state drug prices
3. Bulk purchase and distribute high-priced, broadly-indicated, drugs that protect the public’s health
4. Utilize state unfair trade and consumer protection laws
5. Seek the ability to re-import drugs from Canada
6. Pursue Medicaid waivers to promote greater purchasing flexibility
7. Create a State Pharmacy Benefits Manager (PBM)
8. Pursue return on investment (ROI) pricing and forward financing
9. Ensure state participation in Medicare Part D as Employer Group Waiver Plans
10. Protect consumers against misleading marketing
11. State pension funds assume active shareholder role to influence pharmaceutical company actions

Dr. Sarpatwari described possible legal issues raised by each possible state solution and concluded by offering additional possible solutions: including re-evaluating the use of free samples and “dispense as written” prescriptions and pursuing value-based prescribing.

Jennifer Bryant from PhRMA presented “Prescription Drug costs in Context.” She addressed pharmaceutical spending in the larger context of overall health expenditures. A focus solely on prescription drug costs would not account for the overall increase in healthcare costs.

Ms. Bryant also shared that PhRMA is open to value-based frameworks for pharmaceuticals if certain barriers to doing so can be addressed, including anti-kickback restrictions, data sharing requirements and price transparency reporting clarity.

Tom Brownlie of Pfizer presented, “Balancing the Tradeoffs Between Cost, Innovation, Accessibility and Affordability.” Brownlie noted that innovation leads to generic development and generics now comprise 90% of fills. Brownlie acknowledged that specialty drug costs are increasing faster than non-specialty drug costs, but he noted a Maryland case study that showed in that state that the high rate of increased costs resulted from increased utilization,

22 See note 11.
not price. He also noted that chronic disease management plays a role in increasing drug expenditures.

Mr. Brownlie finished his presentation by noting changes to health plan designs that expose consumers to increasing out of pocket costs for prescription medications. He signaled that the pharmaceutical industry is beginning to embrace the value concept—he cited existing Connecticut law that allows for medication synchronization for fills and the need for ongoing medication management to contain costs and improve patient health.

Following the presentations, Cabinet members engaged in discussion with the presenters. Members learned that there is no clear definition of “specialty drugs.” Members noted that in some cases, inexpensive, ineffective drugs may no longer be available for coverage while drugs needed for conditions such as diabetes are still expensive. Members also noted expenditures in marketing often exceed those for research and development (R &D). Still others expressed concerns about increased cost sharing for consumers and cited Vermont’s efforts at transparency in comparing gross to net costs and efforts at value-based pricing.

In response to a request for the three most impactful strategies Connecticut could consider, Dr. Sarpotwari suggested: 1) increased transparency on systemic and granular levels, 2) the promotion of generic entry into the market, and 3) Medicaid waivers. Mr. Brownlie suggested improved electronic communication/documentation could improve communication and provider patient management.

At the January meeting, two commenters expressed concerns about one of the NASHP Work Group recommendations to allow states to pursue Medicaid waivers to increase purchasing flexibility. The commenters stated that allowing a Medicaid waiver might limit access to certain FDA approved drugs currently required to be covered under federal law.

2. February 14, 2017

Presenters Included:

- Attorney General George Jepsen, Special Counsel Robert Clark and Associate Attorney General & Head of the Antitrust and Government Program Fraud Department, Michael Cole
- Robert Zavoski, MD and Herman Kranc, RPh, Department of Social Services

At February’s Cabinet meeting, Attorney General George Jepsen, Special Counsel Bob Clark and Associate Attorney General and Head of the Antitrust and Government Program Fraud Department, Michael Cole presented on Past and Present Efforts to Address Rising Prescription Drug Costs. Attorney General Jepsen stated after reading an article about rising prescription drug
costs in 2014, his office began to take action. He stated that one of the underlying factors affecting costs of pharmaceutical costs in the United States is the lack of price controls. He noted that patents on high level and very specific components of drugs, including the drug itself, specific actions and delivery systems, limit competition and innovation, especially in the generic market. As previous speakers stated and reports shared with the Cabinet note, he agreed that the barriers to generics entering the market stifle competition for generics.

Attorney General Jepsen’s office found systemic price fixing in the generic market through a multistate investigation in cooperation with the United States Department of Justice (USDOJ). He reported that the USDOJ continues to pursue a criminal investigation while he joined with 16 other states to file suit against six drug companies for alleged price fixing. He noted that drug manufacturers may be paying generic manufacturers to delay the launch of their products to maximize profits.

Robert Zavoski, MD and Herman Kranc, RPh of the Department of Social Services (DSS) presented on “Connecticut Medicaid and Pharmacy.” Like Attorney General Jepsen, Dr. Zavoski expressed the Department’s concern about drug pricing in the United States, however he cautioned the Cabinet to examine these costs viewed through the lens of the total costs of care in the U.S. healthcare system. Pharmaceutical research and the resulting medications very positively impact health in the U.S. Dr. Zavoski noted that many of the childhood cancers he treated as a resident in training had dismal prognoses at that time, but are curable today. Furthermore, other often fatal diseases he saw as a resident, such as epiglottitis, no longer exist thanks to vaccines.

Dr. Zavoski also pointed out that a previous presenter cited new medications to treat Hepatitis C as examples of medications with exorbitant prices, but these costs need to be viewed in comparison to the costs of alternative treatments. The new Hepatitis C medications are curative, whereas the previous treatments used for this disease (which were also quite expensive) merely suppressed the disease and therefore were taken indefinitely over many years, or until the patient suffered serious enough medication side effects or liver failure to require organ transplantation. Lastly, in contrast to the new medications which are pills taken orally, the older treatments were administered via expensive intravenous infusion and required many hospital and physician visits. So in terms of overall cost, although the new medications for Hepatitis C are very expensive today, they are a cure that becomes cost effective in 5 – 7 years. Connecticut Medicaid’s self-insured model allows DSS to view these medications in the context of their total cost of care over many years, and thus we cover these medications widely and focus our efforts on ensuring patients are not re-infected once they complete their treatment.

DSS next examined four recommendations from the Cabinet’s cost containment study and the NASHP Work Group recommendations:

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• Strategies to maximize state purchasing.
• Strategies to address the rapidly rising costs of specialty pharmaceuticals.
• Pricing and incentive design based upon efficacy, performance and comparative effectiveness research.
• Alternative Medicaid pricing strategies.

There were several strategies to maximize state purchasing offered by previous presenters that are not available to Medicaid. The first, joint purchasing arrangements, are not financially viable because of Medicaid’s heavy reliance on the federal government’s successful ability to negotiate price rebates. Medicaid is a federal/state partnership; the Omnibus Budget Reconciliation Act of 1990 requires that state Medicaid programs cover only those medications whose manufacturers participate in the federal drug rebate program in order to get matching funds. Connecticut Medicaid twice investigated the possibility of joint purchasing with non-Medicaid state agencies and was twice informed by CMS that “the purchasing power of the U.S. Government (federal rebate) is not transferrable” and that Medicaid cannot participate with other purchasing arrangements and continue to receive federal rebates. DSS does participate in a joint purchasing arrangement, however with other state Medicaid programs. This pool generates over $750 million in rebates annually. As a result, DSS lowered its pharmacy annual spend by $55.8 million between 2015 and 2016. DSS therefore cannot foresee participating in other joint purchasing arrangements that would yield comparable savings.

Another strategy previously recommended was that legal action be taken to make pharmaceutical prices more transparent. It must be recognized that joint purchasing agreements like Medicaid’s successful rebate negotiations are by their nature best conducted without public scrutiny; no manufacturer would aggressively rebate their prices knowing that their competitors were aware of the actual price.

The last strategy offered by previous experts was for the state and the Medicaid program use a Pharmacy Benefit Manager to support joint purchasing arrangements. One of the strategies used by PBMs to control costs is provider competition, which, under the terms of the State Plan with the federal government, is unavailable to Medicaid programs because they must enroll ‘any willing provider’. DSS, like previous presenters, is very concerned about the rapidly rising costs of specialty drugs, but Dr. Zavoski noted the lack of a clear definition of ‘specialty drug.” DSS is very interested to explore performance-based pricing, however, as previous presenters did, Dr.

25 Ibid at 12.
26 Ibid at 11.
Zavoski called for the FDA to set national policy on biosimilars. Furthermore, he noted that the FDA:

- Approves most new medications coming on the market as orphan drugs, with less rigorous efficacy and safety standards required for approval.
- Approves a larger number of new drugs that in past years which later go on to be recalled for safety reasons that initial research and review failed to identify.
  - Vioxx
  - Seldane

There were several other strategies offered by previous presenters upon which the Department wished to comment. First, DSS uses comparative effectiveness research in its policymaking to the extent possible, offering the Department’s coverage of PCSK9 inhibitors for hypercholesterolemia as an example. Dr. Zavoski cautioned, however, that comparative effectiveness research is still in its “infancy”.

Further, while commercial carriers and employer plan experience supports medication adherence strategies, DSS’ experience with financially incentivizing Medicaid beneficiaries only attracted modest participation.

Finally, Dr. Zavoski concluded his presentation by noting how much the opioid epidemic contributes to tragic outcomes, rising drug costs and rising healthcare costs, which are “almost entirely” attributable to the healthcare industry because of labeling and marketing efforts. He noted that “No high-quality, long term clinical trials demonstrating the efficacy and safety of opiates for chronic non-cancer pain have ever been conducted.”

He described the efforts that DSS undertook to stem the epidemic, including implementation of Section 7 of Public Act 16-43, which limits opioid prescriptions to a seven day supply, naloxone, and other strategies.

He summarized his presentation by asking Cabinet members not to focus on costs to the exclusion of overall context in which pharmaceuticals are used. Herman Kranc also commented on the role of the P & T committee and described some of DSS” utilization review programs and programs such as CADAP.

During the Q & A period, Cabinet members asked whether DSS examined price gouging and Herman Kranc responded that DSS does look for price gouging and reviews wholesale drug prices. In response to a question about state/national policies that might make a difference in reducing drug costs, Dr. Zavoski remarked that advances in drug development, including newer cancer and hepatitis drugs, are safer and work well, reducing long-term costs to the healthcare system.

3. April 18, 2017
Presenters included:

- Jonathan Shaw, VP, PBM Product Development, Product Innovation & Management, CVS Health
- Matt DiLoreto, Vice President, State Government Affairs, Healthcare Distribution Alliance
- Annik Chamberlin, PharmD and Angelo DeFazio, RPh

Mr. Shaw presented, “CVS Health: Understanding the Role and Value of Pharmacy Benefit Managers.” He explained that he works on PBM side, specifically for Caremark, which covers >80 mill people nationally. Some of a PBM’s constituents/clients include public, private sector employers, insurers and Taft-Hartley plans; downstream are the client’s members. He noted that more than 253M people have pharmacy benefits through a PBM, and explained that PBM’s role is to:

- Administer benefits – process claims, manage networks
- Work to keep costs down – negotiating power to reduce drug costs, promote lower cost meds (generics), avoid inappropriate med use
- Improve patient care – patient support, education and compliance activities

Mr. Shaw stated that PBMs result in a 35% average savings to plan sponsors and consumers. Mr. Shaw explained that growth in healthcare costs are expected to exceed GDP, and that this growth is driven by:

- increasing cost of drugs – brand and new, innovative meds
- increased utilization – more clinical indicators for medication use, more people needing meds

Market forces resulted in an 11% trend (which Mr. Shaw defined as the year to year growth in expenditures) for medications costs, but PBMs reduced that to 3.2% through the use of: intelligent purchasing, effective med management and versatile cost strategies. In response to a question that if PBMs have such negotiating power, then why do pharmaceutical cost increases outpace inflation every year, Mr. Shaw briefly identified that the key to managing costs is competition. When there’s competition, there is more opportunity. He used the example of statins, which in a drug type with plenty of competition, so costs can be kept down. He said that specialty drugs are a good example of the impact of limited or no competition on pricing, because they are often unique drugs. With no competition there is less opportunity to negotiate lower prices.

The same Cabinet member countered that even generics see increasing costs and stated that the market has consolidated, there are fewer “mom and pop” pharmacies, with more and larger chains, but we haven’t seen cost savings. Mr. Shaw believes that PBMs are doing a good job, but even a 3.2% increase is an increase. For generics, they do get a lot of headlines. Some single source generics are more expensive, due to reduced competition.
Another Cabinet member followed, asking about the 3.2% overall trend, inquiring what percentage of the PBM’s clients did better? Did worse? And what was the State of CT’s trend? The Comptroller’s Office clarified that the state’s pharmacy trend was significantly higher because it doesn’t use Caremark’s standard formulary, so the costs are more sensitive to price variation.

Another Cabinet member asked if many PBMs have distinct specialty pharmacies to help manage these drugs. Mr. Shaw said that there are specialty pharmacies for these drugs, and the trend in expenditures is typically about 17-18%.

Mr. Shaw then reviewed the importance of competition for the PBMs’ ability to drive down costs through negotiation, providing the example of statins that showed a significant decrease in costs as more manufacturers entered the market. Mr. Shaw reiterated that 85-90% of members take are generics, so there is significant opportunity to leverage PBMs market power to keep costs down. The remaining 10-15% of meds, mostly specialty, are responsible for the highest costs.

Mr. Shaw stated that PBM market power also helps keep costs down. When EpiPen cost increased 150%, Caremark was able to negotiate a 10% increase for clients through negotiated discounts, rebates and price protection.

Mr. Shaw then discussed formulary management, and Caremark’s guiding principles: maintain clinical integrity, use market power to secure competitive pricing and education of members and providers. PBMs pick and choose preferred and non-preferred brands based on negotiated pricing. Clinical care and efficacy is the primary consideration, but when there are multiple medications to treat a condition, Caremark looks for the lowest cost.

When changing a formulary, PBMs work to help members with transitions as needed. There is also a medical exception process for those members for whom the new medication is contraindicated. Historically, PBMs assigned different co-pays to non-preferred drugs, but in the last 5 years the trend has been to exclude coverage of these non-preferred, usually higher cost drugs.

Mr. Shaw then explored the benefit of PBMs on net price versus list price. He noted that when Caremark began excluding non-preferred drugs versus imposing higher cost sharing, the net cost savings increased. When asked whether the price discounts Caremark offers vary by client or payer, Mr. Shaw explained that they vary by payer and manufacturer, but not usually by client, since the PBM usually negotiates as a block.

Finally, Mr. Shaw addressed what he called the “egregious” price increases we’ve seen in recent years, with more drugs experiencing major increases in cost, 100-200% and more. In response, Caremark has introduced a Hyperinflation Program, which identifies drugs that experience these price increases earlier than they historically would. Previously, Caremark might not catch these increases at the system level until planning for the next plan year.
According to Mr. Shaw, some manufacturers would wait until the new plan year, and then increase costs 200-300%, leaving the PBM restricted by the negotiated pricing schedule until the next year. The Hyperinflation program detects these changes sooner, usually quarterly, and lets the PBM address the increases right away.

A Cabinet member asked how this impacts the patient. Mr. Shaw responded that Caremark contacts the patient, provider and pharmacist to discuss the change and options. Another member asked whether the PBM contracts include price protections. Mr. Shaw said that it depends on the manufacturer and drug. Client contracts limit the PBM’s ability to respond to these changes, since many will limit formulary exclusions during a plan year.

Mr. Shaw addressed a question about whether PBMs keep people healthy. He said appropriate and well managed treatment of medical conditions with medications, can reduce the incidence of medical complications, reducing the medical utilization costs. Mr. Shaw said that CVS is more than a PBM – it is a connected healthcare company, with retail stores and clinics, mail order and specialty pharmacy, long term care, infusion, etc. This level of holistic engagement allows for better adherence and identification of gaps in care, minimizing problems and improving outcomes. He remarked that there are cost savings in this model – a statin example showed an increase in member compliance from 43.5% to 52.7% with the addition of pharmacist counseling, resulting in a net savings of $2,710 per patient, including productivity.

A Cabinet member asked if insurers pay the pharmacies or pharmacists for these intervention services? Mr. Shaw said it’s a mix. All PBMs have processes in place to require certain activities of the pharmacies, with reimbursement and other incentives associated. In follow-up, the same Cabinet member asked how this works, who is held responsible for these compliance activities and whether there is any impact on reimbursement? Mr. Shaw said this is a relatively new concept, and while it’s not being implemented broadly and across all plan or payer types, where it is, Caremark is not modifying payment based on these clinical metrics.

In addition to pharmacy care, CVS Health is also exploring patient care, which complements the pharmacy’s function. For example, he said that diabetics can receive more personalized care management of their diabetes through all of the parts of Caremark’s holistic model.

Looking ahead, Mr. Shaw said that specialty drug spend is expected to be 55% of drugs costs by 2020, up from 36% in 2015, despite it reflecting services for a small portion of the population. Factors driving this trend include increasing utilization and prices. The cost for many specialty medications is split, with part of the expenses covered on the medical side, and the drug itself covered as a drug benefit.
Mr. Shaw said that patient adherence is a major problem nationwide. “If you talk to one patient about why they’re not adhering, you’ve basically talked to one patient. Everyone’s got different issues, everyone’s got different reasons.” He said that patient adherence activities, while complicated, can have significant cost savings.

Mr. Shaw also commented that the cost out of pocket expenses is a challenge. Higher cost sharing can impact patient ability to use most appropriate med, or stay on it.

A Cabinet member noted that one thing the Cabinet did not talk about is waste. Many consumers don’t use or don’t finish their prescriptions, resulting in costs with no clinical benefit. This Cabinet member noted that an example of industry practice that can drive waste are 90-day fills. There may be lower up front out of pocket costs, but since a medication or dose could change, a 90-day fill could be inconsistent with changing medical direction. Auto refills are another potential source of waste, since there’s no way to know if a patient is taking the medications, so medication adherence is impossible to monitor.

Mr. Shaw said that CVS Health has studied this, in particular the 90-day and auto refill and hasn’t seen a big difference in costs. He said that once a patient’s medication regimen has been established, 90 day and auto refills can be very beneficial.

A Cabinet member commented that the major criticism we hear about PBMs is their lack of their acting as a fiduciary, specifically Caremark, as the PBM for the state plan. In some PBM-client contracts, the Cabinet member noted that there are provisions requiring that the PBM have fiduciary role. She asked if this was part of the State plan contract. Mr. Shaw indicated that he did not think Caremark was a fiduciary under the state contract, and was not aware of any contracts where Caremark acts as fiduciary.

Another member asked how CVS Health reconciles its role as both a PBM and a pharmacy, since the interests of each seems to be conflicting. Mr. Shaw responded that for the most part, there is no problem. There are internal firewalls to prevent conflicts when the pharmacies negotiate with the PBM. Overall, the vision of each are aligned (promoting med adherence, lower cost medications, etc.)

A cabinet member expressed interest in hearing about the link between pharmacists and clinical care, like the example of a pharmacist flagging that A1C as an indicator of diabetes and referring to the Minute Clinic. She asked about the feedback loop to the primary care provider. Mr. Shaw said that Minute Clinic is on Epic EMR, which allows for very effective sharing of patient information. If there is no electronic integration, the clinical records are faxed to the PCP.
Another Cabinet member discussed a journal article looking at PBMs as “predatory”. He gave an example of Express Scripts per prescription profit increasing 500% since 2003, and asked how effective PBMs are at really managing costs, remarked that PBMs lack transparency and asked why the industry fights transparency. Mr. Shaw responded that negotiations are complex and the landscape changes frequently, so these agreements can be difficult to manage. Pricing is competitive with other PBMs, which should result in industry self-management.

Mr. Shaw continued. He said that transparency is an interesting question since it means different things to different people and there are many aspects to transparency. One area people where people look for transparency are the agreements between PBMs and manufacturers, discounts, etc. He pondered what the end goal of transparency is? Increasing disclosure could result in less effective negotiations, since manufacturers may be less inclined to negotiate robustly since their competitors could then see their pricing and adjust accordingly.

Another member asked about EpiPen, asking that while Caremark shows that its clients’ costs only experienced a modest increase, who might be paying the higher price? Mr. Shaw – said that cash payers, including the uninsured, pay a higher price, but the coupon programs would help to offset some of these costs.

Matt DiLoreto from Healthcare Distribution Alliance (HDA) presented next. He represents wholesalers. Wholesalers are an important link between manufacturers and the pharmacy, hospitals, long term care, etc.

Mr. DiLoreto said that wholesalers are a highly efficient and advanced distribution system in the supply chain. The core function of wholesalers is a very simple one – purchase and store medications and other items from manufacturers, fill client orders and ship to them. He stated that the pharmaceutical supply chain is highly complex and difficult to understand.

HDA represents 34 member companies, each with a unique business model. Based on each client’s needs, his firm will ship medications at least once a day. Anti-trust law requires that they cannot discuss pricing.

He said there are 200 wholesale distributor warehouses nationwide that serve as the middleman for 94% of medications, something that most people don’t think about. Only 6% of drugs go directly from the manufacturer to the pharmacy. The top 25% of wholesalers purchase products from over 1,300 manufacturers. Wholesalers provide a “one-stop shop”. This creates efficiency and reduces burden of finding, ordering and storing products. Wholesalers ship 15,000,000 products to pharmacies every day across the nation. Wholesalers have no control over or role in drug pricing, PBMs or plan designs.
The wholesaler’s focus is to ensure that clients get the medicines they need when they need them. By working directly with manufacturers, wholesalers can ensure that the medications in the stream are FDA approved and legitimate drugs.

Wholesalers purchase from manufacturers based on wholesale acquisition costs (WAC), which are independently created and represent list price, and don’t include rebates, etc. Each WAC is specific to each drug and drug dose. The cost to the wholesaler, based on the WAC, is passed onto the pharmacies.

Mr. DiLoreto referenced the US Today graphic showing the complexity of the pharmaceutical supply chain. Using an example from the graphic, a $250 drug would give a wholesaler a $2.50 profit, supporting the premise that while the wholesaler is a crucial part of the supply chain, it doesn’t add to costs. Wholesalers operate on very high volume, but very low profit margins (around 1%).

Mr. DiLoreto said that the payment model has shifted from a “buy and hold” model to a fee for service model. Under buy and hold, wholesalers could purchase a lot of a product at lower cost, and hold it until costs went up, then sell to increase profit. The industry shifted to fee for service, which reimburses wholesalers for distribution costs. This model helps to stabilize supply chain and costs, as the model is built on the efficient movement of product.

Wholesalers also provide analysis, supply chain security, health IT, EMRs, suspicious order monitoring, contracting services, and more. Pursuant to federal law, there is a new product tracing capability being implemented across the system, allowing an individual drug to be tracked through the supply chain.

A Cabinet member noted that there is an ongoing scandal within the distribution network, where essential drugs are “suddenly” unavailable and then marked up dramatically. The member asked what the industry’s plan is for dealing with this. Mr. DiLoreto was not familiar with the specifics of the issue raised, but said he would research and follow up on this “price gouging” issue. He noted that HDA has testified against this practice.

Mr. DiLoreto noted that many entities have oversight over wholesalers, including the CT Department of Consumer Protection. Drug Enforcement Agency (DEA) and FDA rules also apply.

Annik Chamberlin, PharmD owner of Beacon Pharmacy and Angelo DeFazio, RPh, who owns five pharmacies and two medical marijuana dispensaries, were the next presenters. Their presentation was titled, “Pharmacy’s Limited Influence on the Cost of Medications.”

Ms. Chamberlin began by describing the players involved in medication pricing, including the patient, manufacturers, wholesalers, pharmacies, PBMs and government. When
consumers present prescriptions, the pharmacist knows what they owe, and what their reimbursement is, subject to additional factors. Mr. DeFazio discussed how the lack of U.S. regulation over pricing makes it very complicated to navigate. Each participant/purchaser has different reimbursement.

Ms. Chamberlin said that drug coupons were intended to help offset costs to un- or under-insured consumers, but they actually add cost to the system. Coupons reduce manufacturers’ incentive to lower costs. She provided the example of EpiPen. Coupons to consumers to lower net cost to people, but the list price is the same, which impacts pricing negotiations. This increases overall costs to consumers. Coupons are also usually limited to a short duration or quantity, which leaves the consumer paying full price after the coupon expires.

Ms. Chamberlin said that pharmacies touch every piece of the supply chain – purchasing from manufacturer and wholesaler, dispensing to patient, working with insurance and collecting cost sharing, and providing counseling to patients and providers, but with little or no reimbursement for this counseling.

She commented that pharmacies have no say in reimbursement rates, which have been dropping, as have dispensing fees, which dropped from $2.31 to $1.62 between 2000 and 2010. Mr. DeFazio said that a cliché in the industry is that pharmacies negotiate reimbursement and prices with PBMs, and that is absolutely not true. It is a take it or leave it contract, with small room for negotiation. He has some plans that do not pay a dispensing fee for the pharmacist. Ms. Chamberlin said that much of the reimbursement for medications is less than the cost of the drug, so the pharmacies lose money. Pharmacies can’t easily drop these plans, because they would lose all of those members of those plans. Between 2005-2010 more than 50% of independent community pharmacies operate at revenue margin of 2% or less. Pharmacies have very little to do with overall costs.

She said that large companies hire PBMs to manage pharmacy benefits. Pharmacies are reimbursed at a contracted rate determined by the PBM. There is no chance to negotiate.

Mr. DeFazio said that another issue in industry is narrow network for PBMs, limiting the ability of pharmacies to enroll in network. There are changes from year to year and PBMs can impact pharmacies, since they may end up out of network.

Ms. Chamberlin said that the three largest PBMs control over 78% of the prescription transactions in U.S. Mr. DeFazio admitted that PBMs do a great job administratively, but PBMs morphed into entities that have no direct connection with the patient and drug dispensation. This disconnect complicates the system.
Ms. Chamberlin remarked that the system that evolved can incentivize consumers to use fewer pharmacy services, e.g. mail order, limiting the important face to face needed for effective education and medication management. She said that drug rebates, claw backs, kickbacks, and performance based direct and indirect remuneration fees (DIRs) complicate the fiscal picture more, and it’s difficult to know where the money goes. Transparency is needed to understand this.

She commented that drug manufacturers provide incentives for PBMs to keep drugs on formulary – rebates, etc. – despite no way of knowing if these savings are passed on to a health plan and members—which can lead to increased costs for the retained drugs. For example, the U.S. Department of Justice fined Medco and Express Scripts for accepting kickbacks. Claw backs are complicated. The pharmacy fills the prescription, gets contracted reimbursement, and the additional amount paid by the member stays with PBM.

She said that DIR fees are “backdoor” fees that are imposed on pharmacies by PBMs after the prescription and reimbursement has been processed. For example, a pharmacy processes a claim, ends up with $10 for dispensing. Three to four months later the PBM sends a report noting that some patients had poor medication adherence, and the PBM will take back $5,000 over next 3 months.29

A Cabinet member asked for clarification on the process. Ms. Chamberlin gave an example of the process: A pharmacy buys drugs from wholesaler for $85. The member brings in prescription for the drug, which the pharmacy fills, then submits the claim to PBM for $100 based on the benchmark. The PBM processes the claim and pays it, leaving the pharmacy with $15 gross profit. Months later, the PBM claws back a $7 DIR fee, cutting gross profit by over 50%, from $15 to $7.

Mr. DeFazio said that under the ACA, the intent was to get away from a fee for service model and to focus on quality. Pharmacies have limited ability to impact this quality, but are penalized. He asked the Cabinet to imagine an industry where you don’t know what your end payment for a service will be for several months.

A Cabinet member asked if there is transparency in how the claw back is determined and Mr. DeFazio responded that there isn’t. If he were 100% compliant with adherence, he could still be faced with a 3% claw back from the PBM. The Cabinet member stated that this is asking pharmacists to exceed the scope of their practice, that the pharmacist is being asked to manage a patient’s medical care without a license.

29 See Presentation at 19-20.
Ms. Chamberlin stated that as an example, she received a report from a PBM for the last trimester which showed overall adherence for statins, diabetes, gap therapy, medication therapy management reviews, and requires her to ensure that none of the elderly patients are on high risk medications, which requires calls to the provider. Mr. DeFazio said that if the physician refuses to change the medication, despite a call from the pharmacist, the pharmacist is still penalized.

Another Cabinet member asked what tools the pharmacist gets from a PBM for the pharmacists to meet these expectations. Mr. DeFazio remarked that tools are what he’s been asking for, to take the guesswork out of this, so the pharmacists know what their expectations are and how to comply fairly. He said that there really are no support tools.

Ms. Chamberlin said that these contracts have gag clauses barring them from discussing specifics of the plan, reimbursement, etc. For example, if a patient’s co-pay would exceed the out of pocket cost for a medication, they’re barred from telling the patient. She believes that the extra payment goes to the PBM, not the client.

Mr. DeFazio remarked that there have been examples of employers dropping their PBM and managing this themselves, like Caterpillar, which reduced their costs. There is no transparency, and these efforts have not reduced the cost of healthcare. He asked how is it transparent or reducing costs if a patient has to go to one specific pharmacy for a medication, who then refers to a specific pharmacy to fill that type of drug, but that pharmacy is owned by the PBM.

A Cabinet member said that pharmacists are uniquely positioned to help monitor patients’ adherence, and have a different perspective in patient management. Because this is still evolving, we are not there yet to equitably incorporate all pharmacists, in particular small pharmacies, into the care management team. Pharmacists are the experts on medications, and a part of the care team that is often overlooked.

Ms. Chamberlin said that the system is extremely complicated. Mr. DeFazio agreed and used the example of specialty drugs. How are they classified? He thinks it’s by of cost. He asked why we can’t have complete transparency on where all the money goes. He commented that the U.S. has the best distribution system in the world, but there’s an invisible man behind the curtain, which is the PBM. In order to address this, we really need to know who is getting paid what, when and why, and what the impact on the system is.

A Cabinet member asked, if PBMs truly believe that pharmacists are an important part of the process for monitoring patient adherence, then why do PBMs push patients to use the 90-day refill and mail order?
Ms. Chamberlin cited an example of recent patient, who needed one box of two meds. The PBM required a 90-day fill, but the provider only wrote the prescription for 1, which is not a 90-day quantity. The claim would not go through unless she classified the box as a 90-day fill, but she was able to call the PBM and get a one-time override, instead of sending the patient home with 24 boxes that would have been wasted.

A Cabinet member thanked the presenters and summarized some of the CMS proposals to change pharmacy management for Medicaid, and discussed some of the challenges.

Another member asked for some ways in each area of the pharmaceutical chain where we could reduce costs.

Mr. Shaw said that his personal perspective is that enabling competition between manufacturers can drive costs down, as can the use of generics. He recommended review and simplification of the regulatory pathways to new drug development. He said that excluding drugs will also drive costs down through increased competition by manufacturers to participate, but it has an adverse impact on the member experience.

Another Cabinet member expressed the importance of transparency. Drug pricing is complex, so how can we understand how to fix it? She gave the example of specialty drugs, and the lack of clear definition. She said that we need to know where the money is going, commenting that it is not a crime to make a profit, but it needs to be done in a manner that is consistent with our overall goals.

Mr. DeFazio promoted the concept of PBMs being considered fiduciary, and argued that the limited formulary which impacts member’s ability to use the most clinically appropriate drug in favor of the most affordable is a fiduciary act. Mr. Shaw disagreed, saying that the PBMs are not making the decisions to narrow the networks; that it is the client’s decision. PBMs do not want to be in the position to make those decisions. Mr. Shaw also addressed the premise that the PBMs have a fiduciary role, arguing that they don’t, but instead noted that their role is specified by the clients.

A Cabinet member asked Mr. Shaw how long ago Caremark adopt exclusionary formularies, and noted that clients were told at the time that about 75 drugs would not be available, disproving the premise that PBMs don’t take unilateral actions of this type. He noted that this practice has changed, but that it did begin that way. Mr. Shaw responded that they had taken such action in the past.

The same Cabinet member addressed the issue of fiduciary responsibility, and noted that his membership includes about 60,000 covered lives, and has a PBM that does accept
fiduciary responsibility. That PBM has been willing to do it, and it hasn’t cost the PBM anything. This simply results in a legal obligation for the PBM to act in the best interest of the client.

Another member stated that there are too many middlemen and providers have less power in this relationship. He noted that the wholesalers may only make 1.4% profit, but that results in billions in profits. He suggested that all players should have to report their data to an HIE to help capture the complete picture of the healthcare system costs.

A member asked if any of the panelists could talk about the role of efficacy. She noted that the effectiveness of a given medication should be a factor in determining coverage and pricing. Mr. DeFazio said that the relationship a patient has with the pharmacist and provider promotes efficacy, since pharmacists can help coordinate care that has the best outcome for the patient. If you analyze the costs of Hep C treatment today compared to the costs of managing untreated Hep C prior to medication being available, you would see benefit. Mr. DiLoreto added that the pharmacists are in a better position to know the overall medication regimen a patient is on than the provider. They can identify possible savings or efficiencies.

The Cabinet member clarified that she was looking at this issue from a larger policy perspective, and how these players could work together to optimize the care and reduce costs. Mr. Shaw provided examples of PBMs negotiating with a manufacturer and looking at shifting from rebates to quality incentives. He also talked about indication based rebates – Humira is used for psoriasis and rheumatoid arthritis but may have better efficacy for one than the other, and he suggested that payment could be based on this instead.

Another member offered her shared perspective as someone in the home care environment, where patients often have multiple, conflicting, changing prescriptions that are complicated to manage. Pharmacists are crucial partners for them and should be properly rewarded. Mr. DeFazio reminded everyone that the focus should be quality, and there should be a reward for that services that pharmacists provide.

Ms. Chamberlin emphasized that the increasing prevalence of Health Savings Accounts are making people more aware of the costs than ever before, and that pharmacists are getting more requests for alternate options. Another member emphasized the importance of an HIE for clearly understanding our healthcare system and costs to which the Chair responded that our new state Health Information Technology Officer was in the audience and was working on health information exchange services.

The presentations concluded with an acknowledgment that many of the issues that were raised in the discussion were being actively explored at the state level, and that all of the elements in care coordination, consumer education, need an importance of transparency,
flexibility to respond to consumer clinical needs, and fiscal concerns are critical to improving outcomes.

IV. 2017 Connecticut Legislative/Regulatory/Administrative Efforts Related to Prescription Drug Costs/Oversight of Prescription Drugs

A. The following bills received at least one joint favorable report from a committee—summaries and latest status, including currently filed amendments, are available by clicking on the bill number. (Bills that did not have a public hearing are not included here.)

1. **SB 21** -- An Act Concerning Health Insurance Coverage of Orally and Intravenously Administered Medications
2. **SB 442** – An Act Clarifying the Right to Enforce Antitrust Laws
3. **SB 444** – An Act Authorizing the Health Care Cabinet to Recommend Methods to Study and Report on Total State-Wide Health Care Spending
5. **SB 586** -- An Act Expanding Mandated Health Benefits for Women, Children And Adolescents
7. **HB 5077** -- An Act Concerning the Return of Prescription Drugs to Pharmacies – Public Act 17-109
8. **HB 7010** -- An Act Concerning Opioids and Substance Use Disorders
9. **HB 7042** --An Act Controlling Consumer Health Care Costs
10. **HB 7052** – Governor’s Bill –An Act Preventing Prescription Opioid Diversion and Abuse – Public Act 17-131
11. **HB 7118** – An Act Concerning Biological Products
12. **HB 7123** -- An Act Limiting Changes to Health Insurers' Prescription Drug Formularies
13. **HB 7124** -- An Act Concerning Maximum Allowable Cost Lists and Disclosures by Pharmacy Benefits Managers, Limiting Cost-Sharing for Prescription Drugs and Shielding Pharmacists and Pharmacies from Certain Penalties – replaced by other language

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30 A Joint favorable report is a report compiled by the committee clerk on a standard form for each favorably reported bill. Among other things, the JF report summarizes public hearing testimony and lists organizations that support and oppose the bill. Definition from the Connecticut General Assembly Glossary of Legislative Terms and Definitions, available at https://www.cga.ct.gov/asp/content/Terms.asp#.  
31 This bill passed the Senate on May 3, 2017.
B. The following bills did not receive a joint favorable report:

1. **SB 22** -- An Act Limiting Cost-Sharing for Prescription Drugs
2. **SB 443** -- An Act Concerning the Monitoring of Health Care Trends by the Attorney General
3. **SB 925** -- An Act Concerning the Cost of Prescription Drugs and Value-Based Insurance Design

C. Regulatory/Administrative efforts

1. Insurance Department’s [proposed regulations](#) to review prescription drug formularies as part of plan filings
2. Insurance Department Bulletin [HC-113-17](#) and [survey form](#) -- Annual Filing of Formularies
3. DSS -- See presentation
4. Comptroller’s office -- The Health Care Cost Containment Committee is looking at ways to better control and manage opioid prescriptions, but no actions have yet been agreed upon. Opportunities to lower total medical and pharmacy costs are a part of ongoing discussions between labor and management. The details of such discussions are confidential.
5. All-Payer Claims Database (APCD) -- The APCD is capable of generating reports on pharmacy claims for further research and analysis.

V. Additional Items/Articles Relevant for Further Cabinet Discussion


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32 This bill received a favorable House report and an unfavorable Senate report.
VI. Identifying Themes and Possible Areas for Further Action

A. Possible concepts for state interaction

1. Transparency in pricing, component costs, rebate mechanism, PBM arrangements
2. Value-based pricing
3. Medication reconciliation
4. Medication adherence
5. Community pharmacists’ role in payment reform models
6. Cost-sharing exposure
7. Cost-effectiveness

B. What are the Cabinet’s next steps?

1. Possible solutions within existing authority of Cabinet
2. Administrative Solutions
3. Potential Legislative Solutions
4. Revisit earlier issue areas from Cabinet Report factoring in additional information from 2017
5. Review other states’ legislative efforts in 2017
6. Analysis against principles of potential options for recommendation

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33 A value-based pricing task force was created in legislation in 2016. The task force never convened.
Appendix B

Other Recommendations by Work Groups Considered by the Cabinet

3) Other Legislative Recommendations

1. 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.

2. 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.

3. 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.

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35 In order to preserve the references of public comments to the draft report, the numbering and lettering of draft recommendations is retained in this final report.
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.

4. **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.**

   i) 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 publicly 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/](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.
5. 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 regimen if there was a monthly deductible versus annual. See OLR Research Report, State Laws Limiting Prescription Drug Cost Sharing.

6. 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.

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

i) 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).

8. 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.

b) 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.\(^{36}\)

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.

4) Other Administrative Recommendations

1. 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.

\(^{36}\) The lettering of this recommendation is incorrect. However, to ensure the integrity of the public comment process, which included comments based on this lettering, the incorrect lettering is preserved here.
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).

2. **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.

3. **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.

4. **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 Federal 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.

5. **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.

6. 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.

7. 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.
8. The Office of Health Strategy should further research and refine the following recommendations:

i) 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.

9. 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.

10. 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.

11. 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.
Appendix C

Public Comment on Draft Report

All comments on the Draft Cabinet Report of January are posted on the Cabinet website.

The Cabinet held a month-long comment period. A total of 37 comments were received from a variety of stakeholders:

Industry

1. PhRMA, PhRMA comments 12/12/17
2. Novartis 11/14/17
3. Sanofi
4. Pfizer, Pfizer comments 11/14/17
5. Boehringer Ingelheim comments 11/14/17, 2/5/18
6. Biotechnology Innovation Organization
7. Pharmaceutical Care Management Association (PCMA)
8. Association for Accessible Medicines
9. CT Association of Health Plans (CTAHP), CTAHP comments 12/15/17

Academia

1. Fiona Scott Morton, Yale School of Management

Provider Associations/Providers

1. CT State Medical Society
2. Stephen Smith, MD
3. Velandy Manohar, MD
4. Ross Kristal, MD
5. Susan Israel, MD
6. National Association of Social Workers (NASW)-CT Chapter

Government

1. SIM Quality Council

Advocacy

1. Patients for Affordable Drugs
2. Public Citizen
3. CT Rare Action Network
4. Universal Health Care Foundation of Connecticut
5. CT’s Legal Aid Organizations
6. CT Legal Rights Project/ Kathy Flaherty
7. Arthritis Foundation comments 11/14/17
8. Consumer Advisory Board
9. Planned Parenthood
10. Epilepsy Foundation of CT
11. U.S. Pain Foundation comment 11/14/17

Other/Public

1. Joshua Angelus
2. Linda Bronstein
3. Diane Belford
4. William McKinney
5. Patricia Conway
Appendix D

Work Group Members

1) Value-Based Pricing Work Group –

Members:

JOSH WOJCIK, OFFICE OF THE STATE COMPTROLLER, CHAIR
LESLEY BENNETT, National Organization of Rare Diseases;
BOB CLARK, Office of The Attorney General
ANNE FOLEY, Office of Policy and Management
ELLEN ANDREWS, CT Health Policy Project
SARAH EMOND, Executive Vice President and Chief Operating Officer, Institute for Clinical and Economic Review (ICER)*
KRISTA OSTASZEWSKI, Department of Social Services

Experts:

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2) Cost Determination and Cost Containment Work Group –

Members:

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BOB TESSIER, CT Coalition of Taft-Hartley Plans
MARGHIEGIULIANO, Ct Community Pharmacists Association
JOSH WOJCIK, Office of the State Comptroller
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DR. RAUL PINO, Department of Public Health
TED DOOLITTLE, Office of the Healthcare Advocate
BOB CLARK, Office of the Attorney General*
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• Also provided expert support
3) Legislative and Administrative Initiatives Work Group –

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JENNA LUPI, State Innovation Program Management Office
KATHARINE WADE, Connecticut Insurance Department
JORDAN SCHEFF, Connecticut Insurance Department
SUSAN ADAMS, Masonicare
NICHELLE MULLINS, Charter Oak Health Center
RODERICK BREMBY, Department of Social Services
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Experts:

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NCSL – National Conference of State Legislatures
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JILL ZORN, Universal Health Care Foundation of CT

4) Consumer Healthcare Education Work Group – Susan Adams, Masonicare, Chair

Members:

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ALICE FERGUSON, Consumer Advisory Board
BONITA GRUBBS, Christian Community Action
VERONICA MANSFIELD
LAURA MORRIS, Office of the Healthcare Advocate
MARIE SMITH, UConn School of Pharmacy
SHELLEY SWEAT
SHELDON TOUBMAN, New Haven Legal Assistance Association
RICKAWOLMAN, Department of Children and Families