Value Based Pricing Work Group

Charge:

- **This work group will develop for recommendation to the Health Care Cabinet, a proposal to create an actionable plan to align payer contracting with pharmaceutical manufacturers, PBMs, providers and pharmacies that aligns the value and price of prescription drugs to achieve the aims of improving outcomes and the patient experience, reducing overall medical costs and improving health equity. The recommendations will include meaningful actions that can be taken by state purchasers, regulators, the legislature, or other payers to promote the adoption of pharmacy purchasing strategies that achieve the above goals.**
- **The workgroup will review various pharmaceutical value based purchasing strategies including, but not limited to: outcome based pricing, indication based pricing, value based pricing and value based formulary design.**
- **The workgroup will consider the impact on the cost to the consumer as it evaluates policy options related to the strategies above and make recommendations to ensure consumers share in the potential benefits of value based contracts.**

Recommendations to the Cabinet

1. **Medicaid**
    a. **ADMINISTRATIVE: 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 too 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.
    b. **ADMINISTRATIVE: 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. Concerns about high cost rare disease drugs being targets for exclusions. Can it 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 is 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.

2. State Employee Health Plan

a. ADMINISTRTIVE: Ensure the state employee plan maximizes the value of its pharmacy expenditures by improving outcomes and reducing overall medical costs by:

i. **Make capacity and engagement in value based contracting a consideration in selecting a PBM vendor**

ii. **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**

iii. **Explore opportunities for direct engagement with manufacturers**

iv. 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.

b. **ADMINISTRATIVE: 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.

c. **LEGISLATIVE: Explore the option of expanding access to the state employee pharmacy contract terms, which is now available to non-state public employers, to private sector entities**

i. Currently, such a proposal would only allow other payers better PBM contract terms than they could get on their own but would not change the overall dynamics of the market. However, should the state plan move more toward a transparent PBM contract focused on value and total cost of care the state plan could provide a real alternative to the predominant PBM structure which is ripe with perverse incentives. Expanding the availability of the state's contract terms with its PBM vendor beyond the non-state public employers the state currently allows would require forgoing the state's government exemption from federal ERISA rules and regulations.

3. **State Innovations Model (SIM)**

a. **ADMINISTRATIVE: Recommend to the SIM Quality Council that they seek to add quality measures to the core measure set related to: medication adherence, assistance and monitoring; and communication with patients about drug prices, barriers, the clinical value of each prescription, patient priority setting and alternatives.**

i. A study published last year found that only 30% of patient/provider conversations about three medical conditions with potentially high out-of-pocket costs (breast cancer, depression and rheumatoid arthritis)

involved the costs of medications. Physicians rate the cost of medications as the least important factor to discuss with patients – effectiveness and intended impact is more salient and 35% of consumers taking drugs say a provider has never reviewed their medicines to see if they could stop any (Consumer Reports). A Consumer Reports survey found that a large and increasing number of Americans are not filling prescriptions, skipping doses or cutting pills in half (without talking with their provider). When these drug cost conversations with consumers do occur, consumers are often able to provide important help in finding alternatives, setting priorities, and identifying resources to pay for medications. To improve the number and quality of conversations with patients about medication costs and priority setting, these communications should be formalized, and included in quality measures for new payment models. While nationally recognized measures are developed, health systems, insurers and payers can use patient surveys and other methods to track these communications. (Patient surveys are critical – if patients do not remember or find the conversations useful, they are not effective). When considering these new quality measures, the SIM Quality Council should explore what kind of mechanism should be employed in order to most effectively formalize these conversations, including alternatives that do not directly fall under the responsibility of primary care providers.

ii. It is recommended that pharmacists be added to patient care teams to assist in fulfilling the above requirements

b. ADMINISTRATIVE: As part of its mandate to promote value based insurance design 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.

4. New Programs and Initiatives

a. LEGISLATIVE: 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. California recently passed a law to limit manufacturer coupons to products for which there is no lower cost clinically equivalent alternative, thus 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.

ii. 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.

b. LEGISLATIVE: 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 DAW's upfront. It is not reasonable to expect that patients will navigate to the information publically available on the internet at the time of service, when the prescription is written. However, if the information is prominently posted in the waiting or exam rooms, patients will have a more informed opportunity for inquiry and potentially be able to gain comfort that the prescribing decision was made without conflict. And further, it should be noted that such a standard already exists for the publication of medical research where conflicts are required to be disclosed and readers are not required to independently investigate researcher conflicts. Accordingly, there appears to be a double standard when comparing provider to provider disclosure of conflicts to - provider to consumer/patient disclosure.

iii. Under the ACA drug manufacturers are required to report certain gifts and monetary compensation they give to health care providers. The information is publicly posted at https://www.cms.gov/openpayments/ Requiring such information, as is already available on the government website, be posted in a conspicuous area within a providers office would increase the number of patients who are aware of potential conflicts of interest, allowing them to discuss any potential issues with their provider and perhaps reducing the extent to which providers are willing to accept gifts in the process.

c. LEGISLATIVE: Explore the feasibility of creating a state administered revolving loan program that allows patients that are challenged by the structure of high deductible plans or with significant co-insurance responsibilities the opportunity to amortize the upfront costs incurred at the start of each plan year.

i. Currently certain patients with disease states that require high cost maintenance medications are certain to quickly hit their deductible and or out pocket maximum early in the plan year, creating a significant short term expense. Not all consumers have good options to spread out this cost over the course of the year creating significant financial hardship and sometimes challenging medication adherence. Such a program could provide an avenue for such patients to better manage these costs.

d. **ADMINISTRATIVE: 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

e. **ADMINISTRATIVE: The Office of Health Strategy should review other 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 experience 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.