

UPDATE FROM CONTROLLING COSTS
STUDY GROUP

FOR TASK FORCE REVIEW
9/12/18

Dear Colleagues,

Preparing for the September HCTF meeting, I'd like to offer a proposal that has practical value, is politically viable—although perhaps a stretch, and has been worked on by others who bring substantive background to the issue at hand. The National Academy for State Health Policy model legislation, designed to control the cost of expensive prescription drugs, is the strongest candidate we've reviewed that meets those requirements. You may recall our discussion about this proposal last spring, and reference this Washington Post story that described the bill:

https://www.washingtonpost.com/local/md-politics/maryland-weighs-new-approach-to-curbing-prescription-drug-costs/2018/02/16/781493ea-104b-11e8-9065-e55346f6de81_story.html?utm_term=.f522f041346c&noredirect=on

Trish Riley has provided a copy of the model legislation, plus background material, from NASHP. Included in the link are the legislation (with specifics that still need to be filled in), a blog, and a Q and A conversation: <https://nashp.org/rate-setting/>. Since the bill seeks to directly address the cost of very expensive drugs, I'd suggest we call it the Maine Prescription Drug Affordability Act.

It sets up a mechanism (a commission with rate-setting authority) to set limits on how much any payer has to pay for certain expensive drugs. This commission would have a staff and authority similar to Maine's PUC. It does not restrict patient choice – all drugs still available – but does limit what we pay for them.

This proposal does raise the question: will some drug companies stop providing higher priced prescriptions to providers and patients in Maine? It's worth the risk...would they really do that and risk unflattering PR all over the country? They would still be providing other drugs in Maine since this proposal would only set limits for high cost ones and it could be administratively challenging to exclude some drugs for distribution but not others. I asked Trish about this issue. She will give it more thought and propose some ideas.

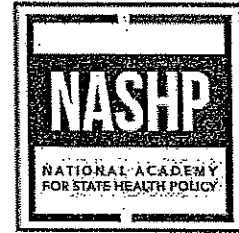
Based on Trish's quick thoughts, the proposal could be amended in several ways to address these issues, including a requirement that any prescription drug price increases that go over a threshold amount set forth in the proposed legislation would be subject to commission review or a requirement that manufacturers who sell drugs in Maine to any payer in Maine must sell to all payers. But more thought and input from all is welcome. I'd like to offer as "open" a proposal as possible for the HCTF's consideration.

I apologize for sending this material in mid-August. But, instead of trying to set a pre-Labor day meeting, I ask you to send written comments. History in Maryland is interesting. The House passed it with broad bi-partisan support. It was not considered in that Senate. We could search the legislative history to review testimony and comments from different perspectives.

Please send comments, if possible, by August 30. I will ask Colleen to help review and summarize them, and we'll send back to you. If you think this proposal lacks merit, please describe your thinking along those lines. If you prefer to suggest another option, please do.

Thanks very much, Brownie

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Drug Rate Setting Model Act Overview

The NASHP model act, “Drug Payment Rate Regulation”, provides a framework to set payment rates for those drugs that create affordability challenges to payors and consumers – typically drugs made by one or a few companies. Health care payors don’t pay what the supplier charges, but rather, they pay rates they developed.

This Model Act lays out an approach to regulate drug payments by building on two well-tested state regulatory models: the public utility commission that sets rates for public goods and services provided by a small number of suppliers and the health care payment rate setting conducted by states and commercial markets (such as hospital payments, nursing home payments, drug payments).

Overview:

This Rate Setting Model Act creates a new state Drug Cost Review Commission with five members and a full time staff to receive and review statutorily-required information submissions from the makers of brand name and generic prescription drug products. Reporting would be triggered by the price of prescription drug products.

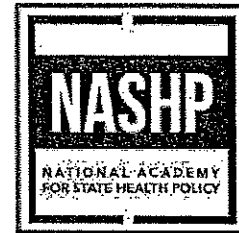
Manufacturer submissions, based on requirements established by the Commission, will be used to determine the reasonableness of the costs created by a prescription drug product. The Commission will have a public process for each drug under review. The Commission will accept analysis and data from manufacturers, payors, consumers, as well as staff or Commission contractors to determine if the cost to the system of appropriate utilization of a drug is commensurate generates excessive costs to the system and whether the drug is affordable to state residents. Proprietary information from any source will be kept confidential by the Commission while other information will be made public. Proprietary information can be used for public research and analysis in a de-identified manner.

The Commission will review submissions that concern drug cost to make a determination as to whether the cost of a drug under review is affordable or generates excessive costs to the system. If the Commission finds that the cost in the state is not affordable to state health care systems and state residents, the Commission is authorized to establish a cost or payment rate for the drug to which all state programs, local governments, state-licensed commercial health plans (including state marketplace plans), and state-licensed pharmacies, and others must abide. These entities are prohibited from paying more for the drugs than the Commission-established rate. The prohibition would be enforced by the state attorney general.

Section 1. Operations of the Commission

The Model Act provisions regarding how the Drug Payment Review Commission operates and its level of transparency include provisions from existing state utility commissions, state health care boards, and

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federal boards. There is a provision to establish a public process for defining and protecting proprietary manufacturer information relative to the variety of information a manufacturer could be required to provide.

Section 2. Required Manufacturer Notice of Introductory Price and Price Increases

The reporting requirements in this section parallel the NASHP Transparency Model Act, which requires reporting for drugs priced at or above specific thresholds.

The Model Act requires manufacturers to provide data and information for new brand drugs coming to market costing more than \$30,000 per year (or per course of treatment) and for the launch of generic drugs costing more than \$3,000 per year (or per course of treatment). Manufacturers must also provide data and information if there is an intent to raise prices beyond a certain threshold: for brands it is 10 percent or \$10,000 in a 12-month period, and for generics it is 25 percent or \$300 in a 12-month period.

There is a third threshold that triggers reporting for drugs that do not meet the price or price increase thresholds above, but whose price or price increase would pose a challenge to financing and affordability.

The data and information to be reported in any instance where reporting is triggered under the Model Act includes market-based data rather than information about research and development. Since manufacturer pricing decisions are driven more by market dynamics and revenue needs, rather than by the sunk costs of research and development, the Model Act requests that market information. The Model Act requires information on the estimated cost effectiveness of a drug, if available.

Section 3. Criteria for Selection of Drugs for Review of Cost

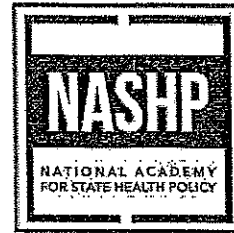
The Commission Chairperson will make the final decision about which drugs should undergo a cost review based on input from the public, the Advisory Board and other Commissioners. The Commissioners can vote to overrule the Chair's decision if that decision lacks consensus among the Commissioners.

Section 4. Determining Excess Costs to Payors and Consumers

This section spells out how the Commission would determine if a prescription drug under review is affordable by determining if costs are excessive. The Model Act adapts a number of provisions for the laws and regulations pertaining the Canadian Patented Medicines Review Board. The Canadian Board reviews drugs for excessive price while the state Drug Cost Review Commission would review if and how a drug produces excessive costs for the state system. The Canadian Board was authorized to review and set prices starting back in 1993, when the patent laws of Canada were changed to give drug manufacturers stronger patent protections.

Fundamentally, the Canadian system and the Model Act focus on financials only – just the price or cost, not the value or effectiveness. The Canadian Patented Medicines Review Board looks at the average

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price in the market and if average price is too high, sets an average price limit; the manufacturer has to prove that its prices average out to the Board price limit. To establish the price limit, Canada uses the average of prices in five countries of the Organization for Economic Cooperation and Development (OECD).¹ Interestingly, the Canadian system creates a high level of pricing compliance: of the 86 new drugs eligible for review in 2015, only five drugs required Voluntary Compliance Undertakings (VCUs) from patentees and of the 103 new drugs eligible for review in 2014, only five drugs required VCUs.²

The Model Act uses commercial payor, provider, and consumer costs, rather than drug price, to determine if the drug price creates affordability problems, and then sets one cost/reimbursement limit for a drug that all state agencies and licensed commercial health plans and their contractors and network providers must use: all-payor rate setting.

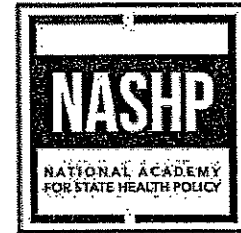
Because of the potential limits on the ability of manufacturers to provide important data, the Model Act relies on health plans and others to provide information useful for Commission deliberations.³

The initial stage of determining affordability relies on data provided by both health plans and manufacturers and publicly available information to determine payor and system costs. If that data and analysis are not sufficient, the Commission can require additional information from the manufacturer that is financial in nature: costs and revenues. The approach is similar to the Canadian Patented Medicines Review Board approach, which looks at manufacturer costs as a second level of analysis if the first level of analysis focused on prices is not sufficient. At this stage, the Canadian Board looks at a company's research and develop (R&D) costs, but only recognizes the R&D spending that equals Canada's proportion of total global drug sales. Similarly, the Model Act proportions the size of the R&D, advertising, and other manufacturer spending that equates with a state's share of national sales.

¹ The U.S. was one of those OECD reference countries but there is a proposal to take U.S. prices out of the calculation because US prices are so high and there is so much non-public pricing activity that cannot be captured in the Canadian formula.

² A VCU "is a written commitment by a patentee to comply with the Board's Guidelines, including adjusting the price of the patented drug in question to a non-excessive level and offsetting any excess revenues that may have been received as the result of having sold the patented drug at an excessive price in Canada. Patentees are given the opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price of a patented drug product sold in Canada appears to have exceeded the Guidelines." (<http://www.pmprb-cepmb.gc.ca/view.asp?ccid=685&lang=en>)

³ Under current law, manufacturers are generally limited in the information they can provide to providers, patients, and payors. They are generally limited to speaking about the data provided to the FDA during the drug approval process and information from the FDA-approved label. Under federal law, manufacturers can provide non-label, pharmacoeconomic analysis to entities that make formulary decisions – pharmacy and therapeutic committees [P&T Committees], but the law takes a dim view of presenting data not on label to anyone else. The FDA is working on guidance to loosen the rules and Congress is debating an amendment on the subject, but the Model Act anticipates that the Commission will have to rely on others (including health plans) for clinical analysis beyond the science pertaining to FDA approval.



Section 5. Commission Determinations, Compliance, and Remedies

The Model Act uses information from, and applies rate setting to, commercial health insurers or commercial health plans, their pharmacy benefit manager contractors, network providers and other licensed health care providers and suppliers, and state agencies. Self-insured health plans are not included because they are regulated by the federal government and state regulation is preempted; however, there is reason to think that these plans would want to voluntarily participate and require their contractors to comply on their behalf as well.

The Model Act anticipates two levels of compliance and enforcement/remedies: manufacturer reporting under Sections 2 and 4; and state agency, licensed supplier, and provider and payor compliance with rate setting for drug financial transactions.

The Model Act does not stop payers from negotiating better deals through the traditional rebate and other manufacturer price concession models, but the structure of the upper payment limit will assure that the cost of the drug is limited throughout the health care system – down to the consumer or patient level – which would be an improvement on the current back-channel discounting to large payer organizations. In today's system, the back channel rebates are not transparent, and more importantly, do not necessarily benefit the consumer at the point of service. An all-payer drug payment would drive what health plans pay pharmacies, what consumers pay when paying out-of-pocket, and what pharmacies will pay for stock and be reimbursed by payors. This transparent rate setting would be an improvement over the non-transparent and complicated system of rebates and other price concessions that only benefit some parts of the health care system.

Section 6. Appeals

Appeals and judicial review are included in the Model Act because there is broad precedent for allowing appeals and judicial review of rate setting body decisions in health care and public utilities.

Section 7. Financing

Financing choices are very state-specific and the Model Act chooses one but there are a number of choices beyond what the Model Act proposes.

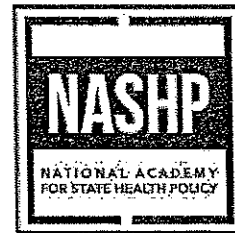
Section 8. Annual Reports

This section provides transparency of Commission activities and drug price trends.

Section 9: Size of Commission, Staffing, and Managing Conflicts of Interest

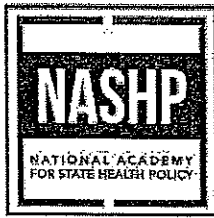
The Model Act specifies 5 members for the Commission and 11 members for a stakeholder advisory body for staggered terms. The governor makes the majority of the appointments.

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There are conflict of interest policies in the Model Act that are adapted from a number of state and federal rules governing similar commissions. The provisions on conflict of interest pertain to Commissioners, Board members, staff, and consultants.

For more information, contact Jennifer Reck at NASHP (jreck@nashp.org)



1 **AN ACT TO ESTABLISH RATE SETTING OF PRESCRIPTION DRUGS IN [STATE]**

2 *Whereas* prescription medications are as important to the health and safety of State residents as
3 traditional public services or utilities such as transportation, gas, electric, telecommunications, and
4 water;

5 *Whereas* [State] has traditionally regulated the consumer price of utilities because of the monopoly
6 structure of the market;

7 *Whereas* the cost of many prescription drugs have become increasingly unaffordable for [State]
8 residents, [State] employers, and [State] and local governments because parts of the prescription drug
9 market are monopolies or oligopolies, and the costs to consumers in these parts of the market are not
10 managed;

11 *Whereas* Canada has a national drug price review board that seldom has to exert its express authority in
12 order for the industry to offer drugs to market at prices that are, on average, 30 percent less than U.S.
13 list prices;

14 *Whereas* the difference between the affordability of traditional utilities and the costs/affordability of
15 prescription drugs is due in part to the active role of our State government in directing how much
16 consumers pay for utilities and the corresponding inactive role of our State government in directing how
17 much consumers pay for drugs;

18 *Whereas* state and federal agencies have a long history of health care rate setting including for brand
19 pharmaceuticals and biologics, and generic drugs to control health care costs;

20 *Therefore*, be it resolved that [State] will create a Drug Cost Review Commission with authority to
21 protect State residents, state and local governments (including their contractors and vendors),
22 commercial health plans, providers, state-licensed pharmacies, and other health care system
23 stakeholders from excessive costs of certain prescription drugs.

24 Overview

25 This Act creates a new [State] Drug Cost Review Commission with five members and a full time staff to
26 receive and review statutorily-required information submissions from the makers of brand name and
27 generic prescription drug products, the price for which triggers reporting. The Commission will be
28 supported by an 11 stakeholder Advisory Board.

29 Manufacturer submissions, based on requirements established by the Commission, will be used to
30 determine the reasonableness of the costs created by a prescription drug product. The Commission will
31 have a public process for each drug under review. The Commission will accept analysis and data from
32 manufacturers, payors, consumers, as well as staff or Commission contractors to determine if the cost to



- 1 the system of appropriate utilization of a drug is commensurate with its benefit to the system and
2 whether the drug is affordable to State residents.
- 3 The Commission will review submissions that concern drug cost to make a determination as to whether
4 the cost of a drug under review is affordable. If the Commission finds that the cost in the State is not
5 affordable to State health care systems and State residents, the Commission is authorized to establish a
6 cost or payment rate for the drug to which all State programs, local governments, State-licensed
7 commercial health plans (including State marketplace plans), State-licensed pharmacies, wholesalers
8 and distributors must abide. These 'covered entities' are prohibited from paying more for the drugs than
9 the Commission-established rate and would be enforced by the Attorney General.
- 10 The Commission can contract-out the cost/affordability analysis or have in-house expertise.
- 11 The Commission will have an Advisory Board of experts and stakeholders.
- 12 The Commission's operations can be funded by a variety and combination of entity-appropriate fees
13 (see Section 8).

14 Section 1. Operations of the Commission

- 15 1) MEETINGS:
- 16 a) The Commission shall meet in public session at least every six weeks to review prescription drug
17 (biologic and pharmaceutical) product information submissions. Meetings can be cancelled or
18 postponed upon the decision of the Chair if there are no pending submissions.
- 19 b) Each public meeting will be announced two weeks in advance.
- 20 c) Materials for the meeting will be made public at least one week in advance.
- 21 d) Each public meeting will provide opportunity for comments from the public.
- 22 e) The Commission will provide the opportunity for written comments on pending decisions.
- 23 f) The Commission may allow expert testimony at the meetings and in Executive Session.
- 24 g) The Commission shall publicly deliberate on whether to subject a prescription drug product to a
25 full cost review.
- 26 h) The Commission shall publicly review a prescription drug product cost analysis and take a public
27 vote on whether to impose a cost or payment limit on payors for a prescription drug product.
- 28 i) The Commission may meet in Executive Session, so long as decisions are made in public.
- 29
- 30 2) PUBLIC ACCESS TO DATA: All submissions to the Commission pertaining to a drug price notices and
31 drug cost review are to be made publicly available with the exception of information determined to
32 be proprietary for different industries that may be submitting information. After public notice and
33 comment, the Commission will establish parameters for what is considered proprietary, and will give
34 particular attention to any pre-market submissions.



1 3) QUORUM: The Commission may make binding decisions in the presence of a simple majority of
2 Commissioners.

3 Section 2. Required Manufacturer Notice of Introductory Price 4 and Price Increases

5 1) FOR PATENTED PRODUCTS

6 a) A manufacturer shall notify the Commission if it is increasing the Wholesale Acquisition Cost
7 (WAC) of a patent-protected brand-name drug by more than 10 percent or by more than
8 \$10,000 during any 12-month period, or if it intends to introduce to market a brand-name drug
9 that has a WAC of \$30,000 per year or per course of treatment. The notice shall be provided in
10 writing at least 30 days prior to the planned effective date of the increase or launch and include
11 a justification as detailed in Paragraph 3 of this Section.

12 b) After consultation with stakeholders and experts, the Commission will establish a third
13 threshold that, when breached, triggers manufacturer reporting for brand prescription drugs,
14 including biologics and biosimilars. The third, distinct threshold will achieve reporting by
15 branded products that have launch prices or price increases below thresholds in (1)(a), but
16 impose costs on the State health care system that create significant challenges to affordability.

17 2) FOR GENERIC PRODUCTS AND OFF-PATENT SOLE SOURCE BRANDED PRODUCTS:

18 a) a manufacturer shall notify the Commission if it is increasing the WAC of a generic or off-patent
19 sole source branded product drug by more than 25 percent or by more than \$300 during any 12-
20 month period, or if it intends to introduce to market a generic drug that has a WAC of \$3,000 or
21 more annually. The notice shall be provided in writing at least 30 days prior to the planned
22 effective date of the increase or launch and include a justification as detailed in Paragraph 3 of
23 this Section.

24 b) After consultation with stakeholders and experts, the Commission will establish a third
25 threshold that when breached, triggers manufacturer reporting for generic and off-patent, sole
26 source branded prescription drugs. The third, distinct threshold will achieve reporting by
27 products that have price increases below thresholds in (2)(a), but impose costs on the State
28 health care system that create significant challenges to affordability.

29 3) JUSTIFICATION: Justification for the proposed launch price or price increases specified in (1) and (2)
30 of this section shall include all documents and research related to the manufacturer's selection of
31 the launch price or price increase, including but not limited to life cycle management, net average
32 price in the State (net of all price concessions but excluding in-kind concessions), market



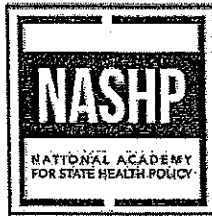
1 competition and context, projected revenue, and if available, estimated value/cost-effectiveness of
2 the product.

3 Section 3. Criteria for Selection of Drugs for Review of Cost

- 4 1) PUBLIC COMMENT: The Commission will keep the public informed about manufacturer price
5 decision reporting under Section 2. The Commission will provide the public an opportunity to
6 request Commission review of the cost of any prescription drug that triggered reporting under
7 Section 2.
- 8 2) ROLE OF THE CHAIR: The Commission Chair will review the public comments and decide whether to
9 undertake a review of a particular drug that triggered reporting under Section 2. The Chair can
10 decide that the Commission will undertake a review in the absence of public comments.
- 11 3) ROLE OF COMMISSIONERS: The Commission members can request a vote on whether or not to
12 undertake a review if there is not consensus with the decision of the Chair.

13 Section 4. Determining Excess Costs to Payors and Consumers

- 14 1) IN GENERAL: Once a decision has been made to undertake a cost review pursuant to Section 3, the
15 Commission review will determine if appropriate utilization (utilization fully consistent with the FDA
16 label) of a prescription drug product has lead or will lead to excess costs for health care systems in
17 the State.
- 18 2) DEFINITION OF EXCESS COSTS: "Excess Costs" is defined as
 - 19 a) Costs of appropriate utilization of a prescription drug product that exceed the therapeutic
20 benefit relative to other therapeutic options/alternative treatments or
 - 21 b) Costs of appropriate utilization of a prescription drug product that are not sustainable to public
22 and private health care systems over a ten-year timeframe.
- 23 3) PHASE ONE DETERMINATIONS: Factors the Commission may consider in determining cost and
24 excess cost include the following:
 - 25 a) The price at which the prescription drug has been/will be sold in the State
 - 26 b) The average monetary price concession/discount/rebate the manufacturer provides to payors in
27 the State/or is expected to provide to payors in the State as reported by manufacturers and
28 health plans
 - 29 c) The price at which therapeutic alternates have been/will be sold in the State
 - 30 d) The average monetary price concession/discount/rebate the manufacturer provides to health
31 plan payors in the State or is expected to provide to payors in the State for therapeutic
32 alternates
 - 33 e) The relative clinical merits of the product under review compared to therapeutic alternates
 - 34 f) The cost to payors based on patient access consistent with FDA labeled indication(s)



- 1 g) The impact on patient access resulting from the cost of the product relative to insurance benefit
- 2 design
- 3 h) The current or expected value of manufacturer-supported, drug-specific, patient access
- 4 programs
- 5 i) The relative financial impacts to health, medical and other social services costs, as can be
- 6 quantified and compared to baseline effects of existing therapeutic alternatives
- 7 j) Other such factors as may be specified in regulation by the Commission.
- 8 4) PHASE TWO DETERMINATIONS: If, after considering the factors in (3), the Commission is unable to
- 9 determine if a prescription drug product will produce or has produced excess costs, then the
- 10 Commission may consider the following:
- 11 a) Manufacturer research and development costs, as shown on the company's federal tax filing for
- 12 the most recent tax year multiplied by the proportion of manufacturer in-State sales to U.S.
- 13 sales;
- 14 b) That portion of direct to consumer marketing costs eligible for favorable federal tax treatment
- 15 in the most recent tax year, which are specific to the prescription drug product under review
- 16 and that are multiplied by the ratio of total manufacturer in-State sales to total manufacturer
- 17 U.S. sales for the product under review;
- 18 c) Gross and net manufacturer revenues for the most recent tax year; and
- 19 d) Any additional factors which can be specified in regulations or that the Commission considers
- 20 relevant to the circumstances, as may be proposed by the manufacturer.

21 Section 5. Commission Determinations, Compliance and

22 Remedies

- 23 1) RATE SETTING: In the event the Commission finds that the spending on the prescription drug
- 24 product under review creates excess costs for payors and consumers, the Commission shall establish
- 25 the level of reimbursement that shall be billed and paid among payors and
- 26 pharmacies/administering providers, wholesalers/distributors and pharmacies/administering
- 27 providers, and pharmacies/administering providers and uninsured consumers or consumers in a
- 28 deductible period.
- 29 2) COMPLIANCE WITH RATE SETTING: Instances of failure to bill and pay at Commission-established
- 30 levels under Section 4 shall be referred to the Attorney General
- 31 a) Upon a finding of non-compliance with the Commission requirements, the Attorney General
- 32 may pursue remedies consistent with the State Fair Market Practice statutes, or in the case of
- 33 intentional profiteering, other appropriate criminal statutes.
- 34 b) It shall not be considered non-compliance if a health care stakeholder obtains price concessions
- 35 from a manufacturer that result in an insurer's net cost lower than the rate established by the
- 36 Commission.



- 1 c) The Attorney General shall provide guidance to stakeholders concerning activities that could be
2 considered non-compliant, in addition to payment transactions where drug costs exceed the
3 Commission established limit.
- 4 3) COMPLIANCE WITH REPORTING: Instances of manufacturer failure to report under Sections 2 or 4
5 shall be referred to the Attorney General for review. The Attorney General may pursue remedies
6 available based on State Fair Market Practice or Consumer Protection laws.

7 Section 6. Appeals

- 8 1) APPEALS: Individuals and entities affected by a decision of the Commission can request an appeal
9 within 30 days of the Commission decision. The full Commission will hear the appeal and make a
10 decision within 60 days.
- 11 2) JUDICIAL REVIEW: Decisions on appeal can be subject to judicial review..

12 Section 7. Financing

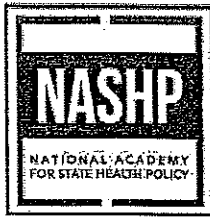
- 13 1) ESTABLISHING AN OPERATING BUDGET: The Commission Chair shall recommend to the legislature
14 financing options within six months of establishment of the Commission.
- 15 2) INTERIM FUNDING Commission will be funded for the first two years with such sums as are
16 necessary but not to exceed \$___ per year until the financing option selected from the
17 recommendations in Subsection 1 are enacted.

18 Section 8. Annual Reports

- 19 1) The Commission shall report annually to the public on general drug price trends, the number of
20 companies required to report because of drug pricing decisions, and the number of products that
21 were subject to Commission review and analysis – including the results of that analysis, as well as
22 the number and disposition of appeals and judicial reviews.

23 Section 9. The Drug Cost Review Commission Membership and 24 Staff Membership

- 25 1) COMMISSION COMPOSITION AND APPOINTMENTS:
- 26 a) The DCRC will have 5 members appointed as follows: 3 members appointed by the Governor, 1
27 member appointed by the Senate, and 1 member appointed by the Assembly.
- 28 b) Initial Appointees serve staggered terms of 3, 4 and 5 years, and subsequent appointees shall
29 serve 5 year terms. The Governor shall name the Chair, and the Chair shall designate the Co-
30 Chair. The Governor will appoint two alternate Commissioners to participate in deliberations in
31 the event a regular Commissioner must be recused.



- 1 c) Commissioners should have expertise in health care economics or clinical medicine.
- 2 2) ADVISORY BOARD COMPOSITION AND APPOINTMENTS:
- 3 a) The Governor will appoint an 11 member Board to advise the Commission on drug cost issues
- 4 and represent stakeholder views.
- 5 b) Initial Appointees serve staggered terms of 3, 4 and 5 years, and subsequent appointees shall
- 6 serve 2 year terms. The Governor shall name the Chair, and the Chair shall designate the Co-
- 7 Chair.
- 8 c) The Advisory Board members will be selected based on their knowledge of one or more of the
- 9 following: the pharmaceutical business model, practice of medicine/clinical knowledge and
- 10 training, patients' perspectives, health care cost trends and drivers, clinical and health services
- 11 research, and the state health care marketplace generally.
- 12 d) The Board must include at least 2 members representing patients and health care consumers, 2
- 13 members representing physicians and providers, 2 members each representing commercial
- 14 payors, government employee benefits, and large employer plans, 1 member representing
- 15 pharmaceutical manufacturers, 1 health services researchers, 1 clinical researcher, 1
- 16 pharmacologist, and 1 state budget office representative.
- 17 3) CONFLICT OF INTEREST:
- 18 a) In appointing the Commission or the Board, any conflicts of interest shall be considered and
- 19 disclosed. Members of the Commission and the Board shall be recused from relevant
- 20 Commission activities in the case where the member (or an immediate family member of such
- 21 member) has a real conflict of interest directly related to the drug product under review.
- 22 b) With regard to Commissioners, Board members, staff and contractors, the term 'conflict of
- 23 interest' means an association, including a financial or personal association, which has the
- 24 potential to bias or have the appearance of biasing an individual's decisions in matters related to
- 25 the Commission or the conduct of the Commission's activities.
- 26 c) A Commission member, staff or contractor with a real conflict of interest with regard to any
- 27 prescription drug under review will recuse themselves from the review. The term 'real conflict of
- 28 interest' means any instance where a member of the Commission (or a close relative), has
- 29 received or could receive either of the following:
- 30 (i) A direct financial benefit of any amount deriving from the result or findings of a study or
- 31 determination by or for the Commission or
- 32 (ii) A financial benefit from individuals or companies that own or manufacture prescription
- 33 drug s, services, or items to be studied by the Commission that in the aggregate exceeds
- 34 \$5,000 per year. For purposes of the preceding sentence, a financial benefit includes
- 35 honoraria, fees, stock, or other financial benefit and the current value of the member's
- 36 (or close relative's) already existing stock holdings, in addition to any direct financial
- 37 benefit deriving from the results or findings of a study conducted under this section.
- 38 4) DISCLOSURE TIMING: In general, a conflict of interest shall be disclosed in the following manner:



- 1 a) By the Commission in the employment of Commission senior staff;
- 2 b) By the Governor, Senate or House/Assembly in appointing members to the Commission and
- 3 Advisory Board;
- 4 c) By the Commission, describing any recusals as part of any final decision resulting from a review
- 5 of a prescription drug product; and
- 6 d) By the fifth day after a conflict is identified or if sooner, in advance of any public meeting.
- 7 5) MANNER OF DISCLOSURE: Conflicts of interest will be publicly posted on the website of the
- 8 Commission. The information disclosed under the preceding sentence shall include the type, nature
- 9 and magnitude of the interests of the individual involved, except to the extent that the individual
- 10 recuses himself or herself from participating in the consideration of any activity with respect to the
- 11 study for which the potential conflict exists.
- 12 6) GENERAL PROHIBITIONS: The Commission, the Advisory Board, staff and third party contractors shall
- 13 be prohibited from accepting gifts, bequeaths or donations of services or property that raise the
- 14 specter of conflict of interest or have the appearance of injecting bias into the work of the
- 15 Commission.
- 16 7) APPOINTMENTS AND HIRING: The Commission shall be organized as follows:
- 17 a) The Governor shall appoint the Chair;
- 18 b) The Chair shall appoint the co-Chair;
- 19 c) The Chair shall hire an Executive Director and General Counsel;
- 20 d) The Executive Director, with the approval of the Commission, shall hire staff; and
- 21 e) Staff positions and salary shall, to the extent feasible, comport with state personnel rules and
- 22 requirements. Exceptions can be made for necessary positions that have no equivalent to state
- 23 government schedules in terms of expertise or function.
- 24 8) COMPENSATION:
- 25 a) Commissioners and Board Members will be paid a per diem and travel reimbursement
- 26 consistent with the State Administrative Procedures Act
- 27 b) Staff will be paid based on State Office of Personnel policies except as described in (6).

Contact Us

States interested in this model legislation will have access to a legislator's guide and additional background materials as they become available. If you have questions about the model act or are interested in technical assistance please contact Jennifer Reck (jreck@nashp.org).

Comments from Rep. Chace on NASHP model legislation:

The prescription drug market is extremely complicated; interwoven in multiple levels of complicated regulation, price disparity and confusion. I am not a professional writer, and publishing articles is not my forte. I beg your patience with this document as it is mostly an ongoing stream of consciousness with regards to my experiences in the prescription drug world. I apologize for changing possessive tenses, poor comma placement and grammar faux pas. I have reviewed this document several times and tried to correct any inconstancy of noun and verb placement. My writing tends to be conversational, if that helps.

I have been both an active participant as a retail pharmacist caring for several hundred thousand patients, as a corporate manager of many self-insured prescription drug programs for employers, to monitoring the billions of dollars of prescription drug contracts, claims and audits in the retail pharmacy industry. I helped implement the supplemental rebate program for Maine Medicaid, having first-hand experience negotiating with drug manufacturers with regards to formulary inclusion and therapeutic responsibility with respect to Medicaid lives and spend. I have served approximately ten years on the board of licensure for pharmacy, and with my 4 years of legislative experience, I have touched a lot of regulatory and contractual pieces in the pharmaceutical spectrum. I do not work for any drug company, retail pharmacy or any other health system. I have no direct investments in any of these companies unless they are contained within my 401k or other retirement investments. I currently own about 1500 shares of stock in Rite Aid, purchased during my previous employment. I am currently a self-employed consultant, with my current focus on helping pharmacy students attain the level of knowledge and work experience necessary to perform the duties of a pharmacist in today's healthcare environment.

It is not hard to stand on the sidelines and look at the price for a drug for Hepatitis C cure, for example, and not roll your eyes and whistle at the same time. Or Epinephrine auto-injectors, or insulin for diabetics. The supply chain of prescription drugs goes from the very source of the active ingredient through the ultimate administration to the patient, and there are thousands of steps in between. It is so complicated, that legislation and regulation has become prevalent in every state, and the policy options that regulators are investigating and implementing are many, and not exclusively:

1. Formulary restriction i.e. non preferred/ step therapy, not covered
2. Transparency of cost from Drug Manufacturer, PBM, Insurer, Rebates, etc....
3. Penalties for certain percentage of drug price increase
4. Reimbursement restriction
5. Reimbursement rate reduction to providers
6. Removing "gag clauses" and other contractual language restriction / removal

There are countless more ways obviously, and each of the options I listed have multiple forms of enactment or requirements for processing, dispensing, or administration. Just quickly off of the top of my head, sometimes it is easier for a patient to get the 100mg drug of a particular product, and then split the tablets for a 50mg dose. Therefore by example 15 tablets of 100mg drug will last the patient 30 days if it is a once daily regimen. This is when the cost of the 100mg drug is obviously less than double the cost of the 50mg drug. This is labor intensive unless the patient does it at home (scored tablets for example make this easier).

Hepatitis C is the condition I will bring up again, because at this time is certainly going to make the top 25 list for any state looking at prescription cost data. Just broadly looking at the population of an estimated 4.5 million Hep-c patients

(<http://www.epidemic.org/theFacts/theEpidemic/USHealthCareCosts/>) , it is estimated to be a \$100,000 life time cost for treatment of an individual patient; and that is without liver transplant. They add that approximately one-third of Hep-C patient eventually require a liver transplant. They further estimate that 1000 liver transplants per year are performed on Hep-c patients, at an estimated cost of \$280,000 dollars. The annual cost of this patient class is estimated at 9 Billion dollars. The cost of a potential drug regimen to “cure” Hep-C? When initially released on the market, the drug or drug combination would be close to \$100k, but now the average is probably much farther south in the \$40k to \$60k range and falling with new drugs in the pipeline and being released. This cure would be for the virus that is the most prevalent of the 4 major viral types. Roughly 87% cure of the 75% of patients with this viral “genotype”. That information I reviewed on an article from 9/2016 that was using drug company graphs of cure / effectiveness of the various drug regimens on the various Hep-C types...

<https://esofosbuvir.com/harvoni-medicine-even-better-sovaldi/harvoni-vs-sovaldi/>. Those prices have declined since then as previously mentioned, and as with most medications will certainly be the case.

So what conclusion am I trying to draw from this example? That prior to these newer “curative” drugs, the cost of treating all Hep-C patients with past lifetime regimens that have been only preventative of disease progression and viral inhibition (vs. eradication), that the lifetime cost of a NON TRANSPLANT patient is greater than the cost of the new drugs released in the last few years. And as cost of prescription drugs are currently increasing in the healthcare spend significantly as a component of total health care dollars, it also means that we have to review what the reduction has been on the medical side. Simply put, medications today are extending lives, reducing hospitalization and even surgical procedures that were once the only treatment. Prior to cholesterol lowering agents, stents and cardiac bypass, for example, heart attacks, stroke and intensive surgical intervention were the only counter measures aside from strict diet and exercise correction. Prevention of many of these procedures are more attainable through prescription drugs. However as people live longer, as we prevent earlier heart attack deaths, medication may actually mean that we are spending money for years of extended quality of life, but still may end up with some of those more expensive and drastic interventions eventually. Improved medication regimens and assessment gave my father 30 more years than we would have had he been as ill in the 1960’s for instance. The medical community has improved diagnosis and assessment. Thirty years ago, Type II diabetics were only discovered when the neuropathies of pain, or worse yet severe infections such as gangrene would show up. How many folks are caught and now treated for the first 5 years of Type II diabetes that 30 years ago were not noticed until symptomatic? Millions. In the past decades those folks were already at loss of circulation, amputation, vision loss, kidney malfunction etc... Remember the 60’s and 70’s when we just thought that older folks just naturally nap after every meal? Symptoms were considered part of aging, but now we can catch it and curb it long before it reaches a symptomatic or true destructive disease progression. But that’s not all—there a 1000 more pieces to this equation. These drugs are also some of the more cost effective out there, provided you aren’t seeking the once daily or weekly regimens that are significantly more expensive. This disease is also offset by lack of diet and exercise and compliance, which I will talk more about later.

At the outset, the Hep C pricing makes the appearance that a drug maker is pricing the drug at a cost that almost equals the cost of lifetime treatment or intervention on more costly healthcare. But not so fast. Remember that government is asking for a piece of this... All brand drugs dispensed or administered in the Medicaid program must provide a 15.1% rebate to the government in order to be allowed inclusion on a Medicaid formulary. If it is not, then a given State like Maine will not receive the 65% (roughly) reimbursement from the Federal government and would have to pay for it on state dollars exclusively. Manufacturers must rebate 11% for generic drug inclusion. The percentage is based upon the AMP (average manufacturer's price) which manufacturers must report regularly.

Additionally, Hep-C patients for example again, are not immune to becoming re-infected should they happen to pursue habits that are likely to re-infect, such as intravenous drug use with shared needles. That moves on to the topic of needle exchange programs which I will not explore here, as it is off topic but illustrates the one tentacle of a massive kilo-tentacle octopus. However, the point remains that should someone need a second dose, it will likely be cumulatively much more expensive than previous lifetime costs significantly. Adding to that is that many patients have been treated for many years prior to adding this new regimen. Perhaps some at this point have reached liver function loss to the point that they need a transplant anyway. Obviously the sooner the better with any treatment, but when you look at the cost of the drug compared to the lifetime cost for a long term patient, there is no question there is a valid trade off in cost. All of these factors are all part of an enormous decision tree that has to be reviewed by the proper credentialed stake holders. In other words, formulary review committees. Because simply put, telling the manufacturer that we will only pay a certain price for their drug, or a certain percentage reduction does not help the problem. A formulary review committee can however set guidelines that make sure that the right patients receive the right drug regimen. This is not in defense of a drug manufacturer's price, this is the beginning of a very long discussion about why up front limits and pricing structure arguments are not so simple.

Now to change gears to the drug manufacturer themselves, we have just as complicated a discussion. At the end of the day, are actual manufacturing costs of the drug in proximity of the acquisition price charged to the healthcare system? Most likely not even close. The cost of the raw ingredients, manufacturing, testing, packaging, distribution and much more are a several year multiple step process that will almost never equate to the "retail" cost on the dispensing / administration side. But given that a laboratory of scientists spent many years researching and developing the drug, testing, reporting to FDA with studies and supporting information and data. I was told in my pharmacy school days that this data amounted to "three tractor trailers full of supporting documents" required by the FDA to review and approve a drug. And for many of these treatments it is common for this process of "idea to injection" so-to-speak is about 10 to 12 years. It is also important to note that this laboratory had to start the clock on the drug patent timeline the moment they drew the molecule on the whiteboard and made the hypothesis (totally unsubstantiated at this point) that they believed they could develop a compound to cure or commute a disease or affliction.

Once this laboratory has put in the years required to perform this process (and this is not performed without payroll and a good deal of expenses), it was not uncommon at one time for most drugs to have only 6 to 8 years (and sometimes less) on the market for the manufacturer's exclusivity. This is partly due to our regulatory environment, and the United States FDA is considered the most stringent in the world. <http://www.jpsr.pharmainfo.in/Documents/Volumes/vol5issue06/jpsr05061302.pdf>. This article from the Journal of Pharmaceutical Sciences & Research is eye opening if you have never seen a flow

chart of the process. Understanding of course that this brief article does not emphasize the years it takes to do this. We in the United States have regulated this level of research and development to protect our public safety, but it would be erroneous to assume that there is not a great deal of added cost to our health system because of it. And so even in the Hep C argument, there are drugs in India that have potentially the same cure rate, and are available for less than \$2000. We must allow safety and demonstration of effectiveness to continue for the sake of public health, but there is no question that regulatory hurdles in our country have an effect on the cost of drug release to the market. I still muse at the fact that for life expectancy, we in the U.S. have the distinction of being 43rd of organized industrialized countries despite all of our efforts to regulate the protection of the public. If our laws and compliance regulations are so beneficial, why do we keep falling further down the list? The drugs in India may be less expensive, but are they safer? I don't know that, but if they want them to be sold in the U.S., they will have to undergo a rigid process for approval, and I assure you the drug will not be less than \$2000 anymore when it gets through (if it gets through).

So then we get into the pitfalls of trying to obtain these products from outside our system. There are countless articles available that discuss the level of counterfeit drugs in the US system vs. the rest of the world. Our pedigree required in US facilities means a lot when preventing diversion. In my pharmacy, I had to be able to trace the origins of the drug from manufacturer to patient, and have proof of every hand-off in between. That is a drug pedigree. From a global market however, we don't have the assertion that the world-wide pipeline is that safe when outside our borders. Counterfeit drugs are much more common in international sourcing points all of the time. And through the internet and global delivery, some of those drugs have made it into the hands of US patients, and even in my role on the board of pharmacy our inspector produced products that he had obtained that were tested and found to be non-compliant with the stated contents. Assays of drugs obtained from outside the US and non FDA compliance, were found to have inadequate / inaccurate drug levels, to none at all, to being an incorrect drug completely. Counterfeit drugs and devices is a real concern, but I do know that the occurrence within our own pharmaceutical distribution channels, it is extremely rare.

Inflation, opportunity cost, and choice. Regulation leads to additional burdens for compliance of the trading partners. Regardless of the intention, this will lead to higher cost. Higher cost leads to greater incentives for higher rebates throughout the network, top to bottom. Higher cost leads to a worldwide epidemic of counterfeit medications. Higher counterfeit medication increases regulatory control on distribution sources and hubs, and thereby drives cost up further. Higher cost leads to more legislation and regulations whereby those of us in politics dictate what the market can and can't do, and by pinching one portion of the equation, we cause a distention at another. It's like squeezing a water balloon before it breaks.

Then opportunity cost comes into play when comparing the expensive long term outcomes of certain conditions through medical care. Did the manufacturer of a Hep C drug figure that \$90k for retail cost is far less than the cost that patient or health system would have to endure otherwise? If they did, then it is an opportunity cost. However, to state that such an opportunity cost is an egregious profit would also negate that the laboratory was engaged for several years in the development, regulatory compliance and the many other pitfalls prior to market entrance. If that drug manufacturer brought 10 drugs to the FDA for approval, chances are that currently only 1 out of 2 will be approved. At one point in my career, it was said to cost \$100 million to bring a drug to the FDA, and more recently I have heard numbers as high as \$250 million. In the 1980's and 1990's, only 1 out of 10 drugs brought to the FDA would make it

to approval. Again that was estimated 20 years ago. So if I live in Alaska off the grid with my own solar power system, I may buy a new flat screen monitor that uses very little power but has great picture quality. And if that flat screen is \$400 at an electronics store, I promise you it will be nowhere near that price when it gets to that off grid home. No roads? Someone has to fly it there and pilots don't work for free. Or sled dog or maybe a 4 wheeler, but beware that it is not recommended that you bounce those around too much! Maybe you can barter, but they are not going to use all that fuel and air time that require expensive annual service and inspection requirements. What that product has gone through to get to the market, is multi-faceted and complicated. When we apply what seems like a simple regulatory "fix", somewhere along that system it doesn't work. It creates backward pressure and response. It forces each of those pieces and partners to enter into different negotiations obstacles to perform their piece of the process. The drug market is no different. So if your good friend in Alaska asks you to borrow \$800 dollars for the monitor, and you find out that you can get it for \$400, you are going to react, aren't you? That is oversimplification, but that is exactly what happens in this market.

Patient choice is another issue. In the mid to late 1990's the FDA allowed direct to consumer advertising (DTC) on television. Choice...watching the evening news that advertisement says to us "ask your doctor or healthcare provider if XXXXX is right for you". I want to be out kayaking with my wife apparently pain free and healthy, or so the ad makes me think. I will ask my doctor if that drug will make that happen for me. The last time I reviewed revenue documents on DTC television ads, those drugs had significantly higher returns than non-advertised, often by tenfold numbers. And since when does someone sitting in their living room understand that a newer anti-platelet drug is the one their doctor should use? Especially whereby many of those folks have never had aspirin therapy to start with, which is very inexpensive (when done correctly and monitored by a health care provider) than the expensive drugs shown on tv. And our clinicians are to blame as well, after all they wrote the prescription. BUT, the opportunity cost for the manufacturers is huge, because clinicians can find many reasons to put us on anti-clotting medications. The rate of diagnosis and "stroke" prevention for atrial fibrillation is going higher and higher. I am not supporting our denouncing any regimen, the correct one is the one that the clinician has truly and thoughtfully pursued for the patient. The DTC market however is real and vibrant, and even experts agree that clinicians may just default to the newer drugs because of initial safety consideration. It is an interesting subject to read, as journals will go back and forth on comparison of regimens and outcomes. Look at what happens when a patient is withdrawn from one of these newer "higher safety profile" medications. There may be expensive and statistically significant events, and studies are still trying to prove the long term benefit of taking these medications. These drugs should be carefully evaluated for use. Are we really determining who needs what medication?

The clinicians will tell you that everyone should be on cholesterol drugs, which frankly should be "put in the water system" as some have said directly to my face. I don't believe it should, unless rhabdomyolysis is a well-known phenomenon that any given individual can assess as more than just muscle aches and fatigue, and is a side effect to these drugs that can be deadly if not caught. But these drugs are prescribed whenever cholesterol readings are are borderline or higher to the excepted norms of today. Those normalization levels keep going lower every year I might add. But patient choice is the expectation that drugs will make us eat what we want, exercise less and my "health insurance" will pick up the tab. "I want choice to eat my junk food and then take a cholesterol drug to fix it", prescribers are going to have that conversation with nearly everyone over thirty years of age. In fairness, there are many whom have good diets and exercise and still have unhealthy cholesterol levels. There are many

valid reasons for every medication on the shelf in a pharmacy, but there are many that could have avoided them with non-pharmacological methods. And so the manufacturers are heavily vested in these types of regimens, because there is a huge opportunity growth there. What are the consequences of this process? I believe we are forcing drug manufacturers to look at models where they can make money to continue to the next therapeutic category. I believe that we will see more drugs in these classes of conditions because of our own free choice. Additionally, the 10 to 12 years of studies to get to the market are significantly less. When a drug compound that lowers cholesterol is brought to the market, there is a significant amount of background exploration and similarity to other approved compounds that the process is much more streamlined.

The negative side to that is that we have medical conditions out there that are seemingly ignored now because the market doesn't exist to build the drug. Just take Lyme disease; there was a vaccination on the market 18 or so years ago – no one bought it, no one used it, they stopped producing it. It is simple economics. There was a patient choice component to that as well. The vaccination was approved in 1998, at the same time the British medical journal The Lancet published the (now widely known false) article regarding vaccination injury and autism links. As a practicing pharmacist, it became alarming how fast folks began to decide that vaccines weren't safe, and the fact that in today's environment 2 decades later we are still fighting to undo that damage. It is still patient choice having an impact on the market. Glaxo Smith Kline stopped producing it. Had it been making them profits, I am sure they would not have stopped. Now for it to be brought back, it is not as simple as just turning the lights back on. It has been a few years now where they are prepping and doing everything necessary to explore and bring it back to market. Incidentally, your dog can get the vaccination, just not a human (to my knowledge at this moment).

In the 1980's, Parkinson's disease drug treatments were improving, initial drugs were short acting and gave only a few years of effect but then enhancements of pharmacology and drug mixing (carbidopa and levodopa combination) longer treatment options with much fewer side effects were being developed and released. But as recently as 2009, I had a good friend with Parkinson's disease as a patient in my pharmacy, and the treatments he was on were essentially those that were available as of the mid 1990's and earlier. It seemed as if the disease management of Parkinson's had fallen right off the radar. He even went to a very well-known specialist in Boston, whom also confirmed there wasn't much more that they could add to his regimen. It's because the component for that disease has now reached a level of complexity that is not going to be simple or inexpensive to determine either a cure or a prevention. It now rests at the level of "palliative care". Begging the forgiveness of the reader, I strongly recommend review of this National Academy of Sciences article. It is technical, but if you read each paragraph you will see the frustration from the manufacturing side. There are many issues that are happening behind the curtain that our lawmakers rarely get to see. <https://www.ncbi.nlm.nih.gov/books/NBK195047/>. So if you no longer have the "disease of the day", is it possible that the market shifts away from research for that disease or condition? I believe it does. This is reasoning behind the Orphan Drug Act. As previously mentioned, the FDA approval of drugs went from a time of 1 in 10 of those submitted to now greater than 1 in 3 (numbers to back this are all over the place, but approval is much higher than 1 in 10 now). It can be correlated to this Orphan Drug Act, which allows manufacturers to get drugs on the market faster for these serious illnesses with very low numbers of patients epidemiologically. To summarize, if it appears to benefit a condition that is so limited in patient need, it helps manufacturers to continue to put time and effort into these conditions knowing that it is not likely to pay them back for

their efforts. Without this act, it is likely these diseases just won't reach the threshold of investment. That is sad commentary, but the fact of the matter is that if we want to open a store that sells Winter jackets exclusively, Miami Florida is probably not the market that you will want to try first. In all seriousness, look at this article with regards to diseases out there and the number of cases reported / identified.

Ask yourself if you were a lab director, and it takes you one year with 4 people in your lab to develop a cure to any one of those diseases, what would you need to charge to make it worthwhile? My very drawn out point is this; It may be true that drug manufacturers are difficult to pinpoint a true cost to a given medication. How much of the orphan drug / disease processes are they involved in? How many will they be involved in if it is not financially viable? Why have we seen such massive mergers in pharmaceutical companies over the years? Do extremely profitable companies look to merge with other companies if they are doing very well? In only but the rarest cases. In the many that I have seen in my career, it was literally the fact that they developed a good drug and just didn't have the resources to get it to market and had to merge with a company with a stronger portfolio and market presence and much more than that...

Opportunity costs exist with the drug ingredient sourcing. IF XYZ Company in a foreign country (or even this country) is the source of a particular medication ingredient, why wouldn't they raise their prices once they see how high the inflation has begun on other drugs? Frankly, it is likely that their costs are rising as well due to the entire impact on the chain of custody stakeholders. My wife and I owned a pharmacy from 2005 to 2010, and watched the period of time where generic drugs actually started to increase in price. That was virtually unheard of unless it was a drug regimen that the FDA labelled as ineffective or lack of effectiveness (DESI drugs – too long to explain here). That's when I began to see wholesaler bulletins where drug ingredient sources were raising prices due to "shortage of resources". In many cases it wasn't just a price increase, but additionally an "allocation" of the product. That meant that we were limited to order only a small amount on a rotating basis if we could get it at all. For the first time in my career, generic drugs that were as low as pennies at true cost, were suddenly going up to \$10.00 and then \$30.00, and much higher beyond that. I had to pay the wholesaler within ten days. But when I would dispense the drug, most often the prescription benefit manager (PBM) would still reimburse at the old rates. If I were to argue about the drug increase to the payer, they would "sometimes" agree to reimburse my invoice cost if I sent them proof. Reimbursing at invoice cost means that I am made whole to my cost of the drug, nothing more. Not a margin to help pay the technician that helped process the prescription, my time on the phone with the prescriber and reviewing the patient profile, the lights overhead, my computer system with my .09 cent per claim transaction fee per submission of claims and on and on and on. I spent three years as a corporate director looking at nearly 1 million prescriptions a day to analyze and catch when this would happen. It meant thousands of dollars in lost revenue over days, not years. And factually, I had the same pricing data as the insurers did, and I PROMISE you that when a drug decreased in price, they had that reimbursement in the system immediately. It was often days and weeks for the price increases to be entered in the system. Again, they would contractually comply with the pricing, but only if I caught it. To have the daily pricing data was not inexpensive to any company, and making sure that contractors were being compliant was more than a full time job.

So does a \$4.00 aspirin or acetaminophen cost \$4.00 in the hospital? Of course it didn't, but when lawmakers and policy makers look forensically at these items, it is very easy to say "We will only pay you a \$1.00 for your time and effort". From my experiences, staffing costs for pharmacists are lower in Boston than in northern Maine. I had vacancies in northern Maine that were measured in several months and years to fill these positions. These positions may pay almost 20% more to get folks to fill these openings. I promise you that the prescription drug program payers did not reflect that in my reimbursements, nor will they. The reimbursement on a given claim will be the same by the same payer regardless of the geography of where that drug is filled. My reimbursement can be at average wholesale cost, minus 17% with maybe \$1.50 fee if I am lucky. This is not an uncommon rate. Using a \$100 drug (at average wholesale price), that means my cost was somewhere around \$78.00, and my reimbursement was \$84.50. In order to pay a pharmacist for an hour, I have to sell a minimum of about 8 prescriptions. Each prescription these days ends up being processed nearly 2 times before it can be dispensed (for following formulary issues, days supply limits/quantity thresholds, incorrect documentation or validation requiring follow up with the prescriber). That is just to pay the pharmacist. Generics are much worse in many cases. I may only receive a profit of \$3 to \$5.00 for a generic drug for commonly dispensed drugs like hydrochlorothiazide or Lisinopril. That's why you would see \$4 drugs at big box retailers and grocers mostly. A brick and mortar pharmacy cannot survive on a margin like that. And they don't ... ask your local independent if you still can find one in your area.

This brings up the gag clause discussions and claw back occurrences that have come up as of late, and this fits perfectly in the discussion. My usual and customary price for a month's supply of a drug like Lisinopril would be \$10.99. And frankly I needed at least \$9 per claim to pay my bills and payroll, and it can be upwards of \$11.00 depending on the pharmacy location. That is regardless of the drug being dispensed. But my contract with most major PBM's was that I was going to have to accept a maximum allowable cost (MAC) for that drug. They know it cost me \$1.32, and with maybe a \$3.50 or \$4.50 dispensing fee, my reimbursement total is going to be \$5 or \$6. HOWEVER, since the patients copay for a generic is now maybe \$15.00 for example, instead of making \$6.32 the patients copay like they did in years past (less than your minimum), they return the copay of \$15.00 to the patient. The pharmacy computer systems do not price these adjudication amounts ever. The price you see on your receipt comes directly from the PBM / insurer, which is a contractual rule. You pay your minimum copay of \$15.00 to the pharmacy, then the PBM claws back \$4.01 from their remit to me to satisfy my retail price. And voila – insurers now figured out how to collect more money from the patient directly through a provider. The anti-gag clauses are now popping up in states like Maine, so that when the pharmacist sees this situation they can tell the patient that the drug is just \$10.99 if they pay cash for it, less than their minimum copay on their insurance. This discussion goes much deeper because now there is an implication to your pharmacy benefit manager. When they express to the plan sponsor, company, ultimate payer, how much they saved the company they will not have this data. Likewise, with some of these dispensed drugs go, it may have been on their preferred formulary because they were receiving some form of rebate from the manufacturer. It will not be reportable if they don't have that drug. They will also argue that it is going to limit their therapeutic review of the adequacy of the drug regimen as well. Insurers express to the ultimate payers that by using their network and programs, they will assess their clients for drug duplication, non-compliance, or even therapeutic insufficiency. They make this as a service component of managing the drug plan, but they are NOT legally required to perform this function. The prescription prescriber and the pharmacist have a legal requirement to perform this function, the insurer's requirement is only contractual with the payer. Ultimately what are they going

to do to offset these losses from the revenue lost from pharmacies catching this discrepancy? I don't know, because each time I think I have seen every trick in the book, a new one comes out. Often times they get pharmacies on prescription audits...simply reviewing prescriptions to make sure that every t is crossed and every i is dotted. The auditors hope is that you can't put your hands on the original prescription order, filled it wrong, or some other compliance failure. Auditors get paid a minimum to audit, but additionally a percentage over and above that rate based upon the omissions they can find. So it is no wonder that in my last audit, it was for 10 drugs and all with wholesale costs of over \$1000 each. It would have been a multiple thousand dollar fine should I have failed on this audit. I did not fail...but about 20 or 30% do fail. Recalling the pharmacy income and profit margin discussions, and observe that the trend in pharmacy industry is to do more with less help. Technology has made it possible for pharmacists to scan in new prescriptions, and then to be able to file the original away for record keeping requirements. If you can't find that original prescription when they come, you may not have the opportunity to get it 'backed up' by the prescriber.

You can buy a new Rolls-Royce Ghost sedan for about \$360,000 dollars. I sincerely doubt that is close to actual material cost. How many will Rolls-Royce sell? How many work at the factory? What is the cost of design for the state of the art systems? A car may be a bad example, because to correlate to a drug cost example, we don't get a Rolls-Royce dispensed if there is a Toyota Corolla which essentially can perform the same function. But in cases that we do? Formulary restriction is how we level the field. We can't just simply dictate to Rolls-Royce that we are only going to pay them what we would pay for the Corolla. After all we just need transportation, and the excesses of the luxury would be hard to explain. And If I am the pharmacy that has to order that "Rolls-Royce" based upon the directions of the prescriber, I will certainly not be able to pay my wholesaler only 50% of what that drug cost if that is what I am reimbursed. I have to pay them the whole amount to order it, usually within 10 days. And Medicaid pays my pharmacy directly, they don't pay the manufacturer. So by stating that we will simply set a limit that we will pay for a medication, there are a lot of folks in the middle that just simply won't (or better yet can't) make that happen. Then I call back the prescriber and state that I can only dispense a Corolla. But more seriously in the drug world, some Hep C treatments are not currently replaceable by a lower cost generic yet. And what was the cost to the manufacturer to produce that product? IN the grand scheme of things, significantly higher than just the cost of the raw ingredients. Remember, there are hands sticking out all along this process each taking a piece, or legislation requiring more vetting, and on and on. At that point, where the most impact occurs is when we force a decision tree with regards to what drugs are formulary and non-formulary.

To consider lower foreign prices and availability albeit aggravating, may not be the panacea that it appears to be. How much is a week's salary in Mexico? In comparison, if a drug is 90\$ for a month's supply in the U.S., will the drug manufacturer be able to sell it in Mexico for that exchange rate in peso's? Not likely given the annual income in Mexico is significantly below that of the US. Do the drug manufacturers withhold those drug products in those countries because of that? They do NOT. So if we hold the manufacturers to these principles of giving us the same price as other countries (i.e an international best price scenario), will they be able to maintain the same market share and profit to continue to provide the drugs to all of us? Not likely. Drug manufacturers currently assess the purchase and dispensing quantities of drugs in Canadian pharmacies, and if the pharmacies appear to be purchasing more than what would be a normal expectation for their patient volume, they research to verify that it is not being resold back to the US. It became apparent to the drug manufacturers that

pharmacies were going much higher in sales volume for certain drugs, higher than what would be expected for their past volume and demand, and manufacturers were able to determine that they were shipping drugs to patients in the U.S. So why would Canada have lower prices on certain drugs? Because Canada is a closed formulary, there is NO patient choice. There is very little physician choice with regards to similar brand name drugs. This is from Canadian law with regards to drug selection by physicians:

Drugs that have not been Approved for Use in Canada ('Unapproved Drugs')

Physicians must not prescribe drugs that have not been approved for use in Canada, that is, drugs for which Health Canada has not issued a Notice of Compliance (NOC).

²⁸ However, there are two circumstances when access to an unapproved drug can be obtained for patient use. The first is when drugs have been authorized by Health Canada for research purposes as part of a clinical trial. The other is when drugs have been authorized under Health Canada's Special Access Programme.

Therefore a valid strategy for negotiation of drug prices and utilization is by having a very large population to negotiate with. If there are 16 million prescription taking patients in Canada, by entering into negotiations for a closed formulary for those patients yields greater opportunity for price reduction because there is less fear of product choice and volatility of the market. Patient choice and DTC advertisements have much less impact and therefore market stabilization. Frankly DTC are still mostly not allowed in Canada, and when they are used it is very strict.

This out of country pricing has nothing to do with allowing drug manufacturer's to run freely with pricing. This is not saying that we have to remove all patient choice from their therapeutic regimens. This is not about stopping medical providers from doing what is right for their patients. Tools and policies that make across the board reimbursement cuts, adding audits on price percentage increase thresholds a, and all the other policies we employ can only temporarily make any movement in the industry. Because when we do that, there is a counter effect. In Maine, we just removed an insurer's requirement of step therapy for formulary non preferred drugs provided the patient has already met the conditions of failure on preferred formulary drugs. Understanding that with type 2 diabetes again, the \$20 dollar drug in combination of diet and exercise can bring the patient into blood sugar compliance as well as the several hundred dollar injectable. The step therapy therefore would show that for 99% of patients, the \$20 drug is more than adequate. So to get to the weekly injectable, the practitioner will have to prove why the patient could not tolerate the \$20 regimen. This is logical, especially when a provider and patient diligently tried the preferred regimens and had legitimate failures. The reality is that in these case, an extremely high percentage of patients should be adequately treated on the first line drug, and this prevents the open access to a \$90 brand drug when it has had a similar therapeutic substitute available at one third of that price. I have patients who have flat out stated that they wanted BRAND C, but their doctor told them they have to use generic A and B first. Formulary aversion and work arounds have become a sport in the health care industry. Overbilling and needless therapies are born from providers capitalizing on whatever tools, drugs, procedure codes or therapeutic indicators they can to make their payroll. By the way, the \$20 dollar drug is not on the television commercials. The several hundred dollar weekly injection is though. Practitioners have learned a new question to the patient as well. Do you have good prescription insurance? If you do, they may write the weekly regimen for you, because, well you have good insurance so what's the difference?

Inventory cost and high dollar transactions also occur when a Medicaid program prefers long lived brand drugs on its' formulary. The reason is because the consumer pricing index penalties (CPI-U) have been levied on that drug that makes the manufacture rebate often significantly more than the 15.1% required rebate. The reason is that the assumption is that the drug has been on the market for so long, that in calculating the current cost basis of the medication it should not need to be as high as it was when first introduced to market. Basically. And factually there are brand drugs that are on the market that can be very expensive brands, but these penalties have lowered their actual cost to the Medicaid program that are well below the generic cost, and therefore financially beneficial to the Medicaid program. However, the pharmacy must still pay the very high price to put that drug on the shelf, as its' list price is still very expensive. That means the pharmacy puts a lot of capital in inventory cost, which is very expensive to do. High priced inventory requires a large amount of money to maintain and still make payroll, especially when the profit upon remittance is really not profit unless that entire bottle is dispensed or administered. A drug can cost easily \$400 to \$500 dollars to put on the pharmacy shelf. Usually they are bottles of 100 or more doses. Prescriptions for these drugs do not come in quantities of 100, nor would they be covered for quantities of 100, because if it is a once daily med it is going to ask for 30 tablets to be dispensed, twice daily would be 60 tablets, and three times a day would be 90. There are a minimum of 10 doses left over, and even dispensing 90 tablets in one prescription will not bring in enough remittance to pay for that entire bottle of 100. Typically maintenance drugs are dispensed in 90 day supplies, and will still not often fulfill a "unit of use" bottle situation. There are more unit of use packages out there than many years ago, but it is still very common to have to break bottles into partials. Additionally, the ten tablets are not enough to fill an entirely new prescription, and therefore the pharmacy must now order another bottle at potentially \$400 to \$500 dollars, and they have not even paid for the first one. Any reader that has been to a pharmacy will absolutely be able to recall a time that the pharmacy has stated that they did not have enough med to fill the prescription. Inventory systems have had to be built at a great expense because no pharmacy can simply maintain inventory levels like they could in the past. And even when normalizing for today's costs vs the past, we are talking about several fold increases in just the last 20 to 30 years and again at decreasing profit margins resulting in decreased staffing and on and on. At the same time, the health care payer organizations are increasing the out-of-pocket share of cost to the patients, notwithstanding the extremely high deductibles on the medical side as well as premiums.

Medicaid is not the only payer that puts pharmacists in this predicament of drug dispensing limits, the private insurers have very similar limits on dispensing quantities, but the difference is the private carriers will almost NEVER allow the brand drugs that the Medicaid program supports. The PBM's and insurers are not going to get rebates back from the manufacturer that will be high enough to satisfy the ultimate client / health program. A brand name oral contraceptive from 40 years ago is not treated to CPI-U penalties in the private programs, and therefore the generics are almost always the best option both therapeutically and financially. This is not always the case, but it is most often. This product inconsistency that now appears because of "private formularies" versus Medicaid formularies is absolutely adding to this inventory burden. In other words, pharmacies are stocking for high brand usage on Medicaid, and high generic usage on alternate payer sources and has essentially the worst of both worlds. When thinking about outdated medications in the pharmacy, there is often no allowance of returns for partial medications that are expiring. The manufacturer's are not making a lot of money if any on these brands either, because in some cases the penalties have brought them down to a zero cost

to the Medicaid program. We would all be better off if they just produce it as a generic and stop these high dollar transactions and inventories.

The last point I am going to make about prescription medication is patient compliance. Given every variable that has been discussed so far, the last piece is to me the most important. Knowing that at the end of the day, most providers are trying to do their best for what is in the best interest of the patient, we still have the "you can bring a horse to water" analogy. Depending upon whose statistics you prefer to read, the bottom line is that prescription medication compliance is still probably 50% overall. You can factor in differences in conditions, therapeutic consequences for noncompliance, but regardless this is significant. A health plan then realizes that a significant portion of their outlay is going unconsumed. Bringing it back to the pharmacy is a terrible idea, as well as currently still against the law in most cases. That opens a whole new discussion on storage requirements, potential adulteration and the previous risk of entering counterfeit medications into the system. However, the point remains that the human component is still the part that needs to be reined in. Just about everything that I have discussed in this article can be assessed and hopefully managed through a true P&T committee. Wellness programs, formulary scrutiny, proper assessment and prescribing, compliance programs to keep patients on the right path to better health. When I make wooden baskets for Memorial Day flowers, the slats of wood that are left over make very good small pieces to finish off some of my Christmas display pieces. If I am told that I can no longer make the baskets, I am not likely to buy premium pieces of wood to cut up into smaller artifacts because it just isn't worth it. That is an oversimplified analogy, but it is what we are doing to our drug industry.

And as a long time provider of medication, there are no easy answers to complex situations such as the prescription drug industry. Most policy decisions end up focusing on simple fixes that create more complex problems and conditions. It is easy to look at an expensive regimen and try to negotiate it down to a lower price like at garage sale. I have watched prescription drug prices increase more and more dramatically over my 30 plus years in pharmacy. I have watched reimbursements continue to decline. We have seen the out-of-pocket patient costs and deductibles raising significantly. We have watched the stress level of healthcare providers going up. We have seen dramatic increases in policy implementations trying to stop this, but it continues to escalate. We are seeing the mortality rates in the US getting worse in this same time period. The best scenario I have seen used in the totality of prescriptive health care, is to carefully prescribe and not overprescribe, carefully and thoughtfully perform drug utilization review, and bring all of the parties to the table. Wellness programs are developing rapidly, and frankly are going to be the most beneficial cost reducer in the prescription drug market. High blood pressure, diabetes, and depression are probably the three largest outlays in the prescription drug world, and a great deal of it is lifestyle and prevention understanding. Diet and exercise. WE can't simply point our fingers at the manufacturers, the insurers, the PBM's, the pharmacies, the healthcare providers. I cannot picture any single legislative bill or rule that will make this system work to reign in the high cost of prescription drugs. It takes all stakeholders and trading partners to weigh in and work their areas of expertise, but recognizing that it has to be beneficial to the whole. Legislation and policy making seems to incentivize work arounds and unnecessary markets. I believe we should negotiate from zero inclusion. Why and when should your therapy be allowed in the market place? Then the committee all weigh in. Healthcare providers dictate therapeutic conditions based upon sound reasonable judgement. Payers dictate terms of allowance and formulary placement. Wholesalers and pharmacies weigh in logistics and dispensing issues.

Having a manufacturer negotiating on behalf of a portfolio of their drug products is better than just putting restrictions on the extremely expensive ones. If a drug is going to be \$80,000, wouldn't it be more prudent to have 5 dispensed with compliance at \$400,000 rather than allowing ten but offering (or demanding) only a 50% reimbursement? That may be the same cost number, but the trading partners along that paradigm can budget on the first scenario. They can plan. There would be less paperwork, less stress. Less inventory. Less waste. Less fraud. Less audit. Less transactional costs. Less overprescribing for unnecessary occasions. I would ask that the manufacturer demonstrate to us that they are able to reduce costs elsewhere. Help us through getting better compliance models with their medications. Philip Morris is now making commercials that state that smoking is deadly. Instead of direct to consumer ads, I would love to see manufacturers doing a non-branded commercials about the impact of improper lifestyle choices and compliance. Instead of that happy couple out in kayaks, talk about the number of folks that thought medicine would let them eat anything and have a terrible lifestyle. Show them that medications at that point are just barely giving some a quality of life that is heathy and happy. Preventative medicine is the cure.

