

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:

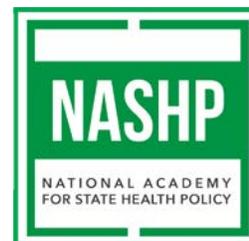
This Rate Setting Model Act creates a new state Drug Cost Review Commission with five members and a full time staff to receive and review statutorily-required information submissions from the makers of brand name and generic prescription drug products. Reporting would be triggered by the price of prescription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



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.

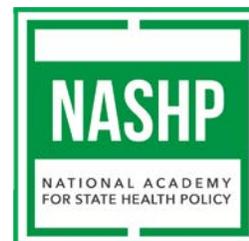
Section 3. Criteria for Selection of Drugs for Review of Cost

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



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.

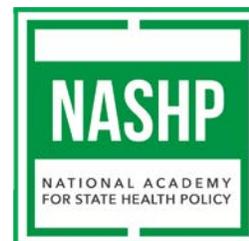
Because of the potential limits on the ability of manufacturers to provide important data, the Model Act relies on health plans and others to provide information useful for Commission deliberations.³

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.

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