# NASHP Model Drug Price Transparency Legislation Q&A

The National Academy for State Health Policy (NASHP) first released model transparency legislation in 2017. Since then, six states have passed drug price transparency legislation. NASHP's revised model legislation represents the next iteration of transparency legislation. It incorporates a minimum data set to reduce reporter burden and yields standardized, actionable data from across the supply chain. This data can help states understand what is driving high drug prices and enables comparisons across states. This 2.0 version of NASHP's model transparency bill also contains stronger enforcement mechanisms, such as allowing a state to invoke subpoena authority when needed. NASHP convened a workgroup of states in 2019 to develop this new transparency model and minimum data set in collaboration with Mathematica Policy Research.

**Why is this transparency legislation necessary?**

Manufacturers frequently claim high US drug prices are necessary to support research and that lowering them would hamper innovation. The black box of secrecy surrounding drug prices, however, makes it difficult to test this and other justifications. This model bill opens up the black box of drug pricing by requiring manufacturers to provide information about costs and revenue related to drugs with price increases (or launch prices) that exceed a predetermined threshold.

**Who has to report information under this model legislation?**

Accurately understanding high drug prices requires looking across the entire supply chain. For that reason, this model requires reporting not only by manufacturers, but by pharmacy benefit managers (PBMs), wholesalers, and insurers as well. (States with an all-payer claims database may be able to generate the reports required by insurers rather than create additional insurer reporting requirements.)

**What will data generated as a result of this model legislation tell us?**

The minimum data set was designed to provide answers to the following core questions:

<u>Pharmaceutical manufacturers reporting requirements for drug price increases:</u>

- What is the recent history of the manufacturer's price (wholesale acquisition cost - WAC) for this drug before rebates or price concessions are applied?
- What has been the recent history of the manufacturer's revenues and costs for this drug group?
- How much has the price of this drug before rebates (WAC) changed since launch or acquisition?

- How much do major components of cost (manufacturing, marketing, etc.) contribute to the manufacturer's current cost of this drug group?

Pharmaceutical manufacturers reporting for high-priced new drugs:

- What is the price of this drug (WAC) before rebates, and how much does the manufacturer project this drug will cost per patient in the next year?

Insurer/PBM/wholesaler reporting:

- What were the costliest drugs (individual National Drug Code - NDC) that insurers purchased *before* rebates and price concessions last year?
- For each drug, how much did insured consumers spend (including cost sharing) on all formulations from the same manufacturer?
- For each drug, what was the total value of rebates and negotiated price concessions from the manufacturer? What was the total value of pharmacy dispensing fees?
- How much of the total value of negotiated rebates and price concessions from the manufacturer was retained by PBMs? Retained by wholesalers? Passed on to consumers?

**What data elements must be reported?**

In order to allow states to answer the key questions listed above, reporting entities must provide the following data points:

- Manufacturers (for price increases): Drug name and other identifying information; launch date; five-year history of WAC, US, and state sales volume for the drug; and justification of price increase including a five-year history of revenue and costs associated with the drug. The specific factors that must be included in this cost justification are manufacturing, research and development costs, capital expenditures, patient assistance programs, price concessions, marketing, and administrative expenses. These data elements will yield an understanding of the manufacturer's profit margin on the drug.

- Manufacturers (for high-priced new drugs): Drug name and other identifying information; projected patient volume and revenue; and WAC at market introduction.

- PBMs and wholesalers: Minimum and maximum WAC for each drug; the volume of the drug; and negotiated rebates, ingredient costs, and dispensing fees. These data elements will yield an understanding of the cost that PBMs, wholesalers, and pharmacies represent.

- Insurers: Four separate lists of the top 25 prescription drugs for the last calendar year, before enrollee cost sharing, representing the greatest total spending; the greatest total spending *per user*; the highest year-over-year increase in total spending; and the highest year-over-

year increase *per user*. These data elements will provide an understanding of the drugs creating affordability challenges for payers and consumers.

**What are the thresholds for reporting?**

- For brand-name drugs: A 20 percent increase per WAC unit during any 12-month period;
- For generics: A WAC unit price of $10 or more, and a 20 percent increase per WAC unit during any 12-month period;
- For new drugs: A WAC of $670 or more; and
- For PBMs and wholesalers: The state will require PBMs and wholesalers to report on specific drugs identified as being of interest following state review of manufacturer and insurer reports (see above).

**How many drugs will be reported on?**

The threshold for manufacturer reporting was designed to generate reporting on a reasonable, actionable number of drugs. Our analysis suggests that manufacturers will report on approximately 30 drugs triggering the brand threshold per year and an additional 30 drugs triggering the generic threshold per year.

**What can a state do with this information?**

To address rapidly rising prescription drug prices, purchasers and policymakers need to know which drugs are driving spending, and why their prices are so high and increasing so rapidly. Whereas current transparency laws limit manufacturer reporting to elements already in the public domain, this 2.0 version requires additional reporting to yield an understanding of costs along the supply chain, testing common public justifications of high prices against more fully transparent accounting. The data reported by manufacturers, PBMs, wholesalers, and insurers will provide a basis for effective state action based on an awareness of the highest-cost drugs and the factors contributing to their high prices across the supply chain. For example, as a next step beyond this model act, a state may wish to put forward drugs with high and fast-rising prices as potential candidates for review by a drug affordability review board, such as the one recently passed in Maryland. Other states, such as Oregon, are exploring taking action to redesign preferred drug lists for Medicaid.

**How does this model deal with proprietary information?**

This 2.0 version of NASHP's model transparency bill builds off existing transparency measures, but requires additional information that is not otherwise publically available, including specific information about past and projected costs and revenues at the drug level. Some of this information may be considered proprietary. The model bill protects proprietary information. For example, while the state agency must publish an annual transparency report, the state agency may report only aggregated data and must ensure that the data in the report does not reveal information specific to any individual reporting entity. This language is similar to the confidentiality provisions that prohibit insurance

departments from disclosing information received from insurance companies regarding how their products are priced, allowing states to protect proprietary information received from insurance companies while still providing important public information. This bill enables the same approach to confidential data received from manufacturers, PBMs, and wholesalers.

**What enforcement mechanisms are included?**

This 2.0 version of NASHP's model transparency bill contains strong penalties for failure to report ($30,000/day). Importantly, it also allows states to invoke subpoena authority if reporting entities do not provide the required data or if the data they provide is unclear or inadequate.

**What are the next steps?**

NASHP and its work group will identify and support states advancing transparency legislation and will track those efforts on its website. States interested in this model legislation will have access to NASHP's technical assistance. Please contact Jennifer Reck with any questions or for more information.

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