Chart: How NASHP's Model Act Addresses Legal Experts' Concerns

This chart summarizes how NASHP's Model Law to Protect Consumers from Unsupported Price Increases addresses the concerns raised in its legal analysis, NASHP's Proposal for Imposing Penalties on Excessive Price Increases for Prescription Drugs, written by policy experts Michelle M. Mello, JD, PhD and Stacie B. Dusetzina, PhD. The report includes recommendations to assist states in avoiding legal challenges and describes how states can leverage price and value analyses conducted by the Institute for Clinical and Economic Review (ICER).

Report Recommendations:	**Model Act:**
To avoid legal challenges based on the dormant Commerce Clause, the penalty should only apply to transactions within the state.	The model act limits the penalty to only sales of products within the state (Section 3.a and 3.b)
To reinforce the nexus to in-state transactions, states could limit the reach of the penalty to manufacturers that either maintain a place of business in the state or sell over $100,000 worth of products in the state per year.	Penalties only apply to manufacturers who "have at least $250,000 in total annual sales within the state in the calendar year for which the tax is assessed" (Section 3.c)
To avoid patent preemption claims, prohibitions on excessive price increases should not apply solely to on-patent drugs, they should also include generic products.	The model act applies to both patented and generic products included in the ICER analysis.
To avoid patent preemption, limit the magnitude of the tax. If the penalty is close to 100 percent, courts may see it as an attempt to deny patentholders the right to set their own price.	The model act imposes a penalty of 80 percent of sales within the state (Section 3.b).
To avoid patent preemption, if a state specifies a time period in which a tax penalty will be imposed, it should not be pegged to the period of time when the drug is on patent.	The model act does not specify a period of time related in any way to the period of time that a drug is on patent.
To avoid a challenge based on vagueness, the definition of excessive must be specific and give adequate guidance to the decision-making body about how to evaluate price increases.	The model act is very specific and utilizes ICER's Unsupported Price Index Report as the basis for determining which drugs will be subject to the law(Sections 2.b and 3.d).
States should **publish an annual list of offenders.**	The model act requires the publication of an annual report describing, among other things, the manufacturers who have been subjected to penalties and the amount of the penalty (Section 4.c).
The law will have maximum effect if the **revenue raised is earmarked** for providing consumers with direct relief from high drug costs.	The model act requires that revenue generated be segregated into a separate account and used to offset costs to consumers (Section 4.a).