Q&A: A Model Act to Prevent Excessive and Unconscionable Prices for Prescription Drugs

How does this model act stop price gouging?
Recent price hikes for insulin and other drugs have awakened the public to often unpredictable and extraordinary increases in commonly used drugs. This model act prohibits manufacturers from hiking drug prices outside of certain market conditions that might justify a jump in price. Noncompliant manufacturers face fines and must stop charging the excessive price.

Maryland’s law prohibiting price-gouging was struck down, how is this law different?
Maryland’s 2017 anti-price-gouging law was struck down by the 4th Circuit Court of Appeals for regulating the price of transactions that occur outside Maryland – a violation of the dormant Commerce Clause. This ruling pointed to the Maryland law’s reliance on wholesale acquisition cost (WAC), the price wholesalers pay to purchase drugs from manufacturers in a transaction that might take place outside of the state of Maryland.

NASHP commissioned a legal analysis to strengthen state approaches to prohibiting price-gouging and incorporated several of its strategies into this model act, including specific language to provide a stronger nexus between the model act and in-state transactions, such as a requirement for wholesalers to maintain a registered agent and office with the state. Many states already require wholesalers to be licensed and the requirement to maintain a licensed agent and office is a relatively low burden and is readily available as a commercial business service for a small fee. It is a common requirement in many states for out-of-state corporations.

What must a state do to implement this law? Which agencies are involved?
The model act requires a state’s state employee health plan to notify the state’s attorney general if a prescription drug price increase exceeds a threshold. Upon notification, the state’s attorney general investigates the price increase based on information that must be supplied by the manufacturer. If the attorney general determines that the price increase is in violation of the statute, the enforcement actions described above are set in motion.

Which drugs does this model act address?
This law applies to generic and off-patent drugs only because federal law protects manufacturers’ ability to set prices for patent-protected drugs.

Why aren’t biosimilars included in this model act?
Biosimilars (similar to generics but for biologics) represent an emerging market with the potential to offer significant savings off biologics. However, the market has been plagued by drug manufacturers’ attempts to delay or block the entry of biosimilar competitors. For example, though there is a biosimilar for Humira available in Europe, it won’t enter the US market until 2023. With so few biosimilars on the US market, pricing standards for biosimilars have yet to be established. While a state may wish to monitor the biosimilar market and include...
biosimilars with an appropriately calibrated threshold to an anti-price-gouging law in the future, including biosimilars at this point with the limited data available to set appropriate thresholds, may inadvertently inhibit the emerging biosimilar market in the United States.

Is price-gouging a problem in generic and off-patent drugs?
There have been multiple, well-documented and egregious cases of price gouging that could have been prevented – or reversed – by this act. The most notorious example is Turing Pharmaceutical’s 2015 decision to raise the price for the off-patent drug Daraprim, used to treat the parasitic disease toxoplasmosis. Turing raised the price from $13.50 to $750 a pill – the price at which it remained until the US Food and Drug Administration (FDA) approved a generic for Daraprim in February 2020.
More recent examples have been revealed by manufacturer reporting on drug price increases required by California’s drug price transparency law:

- Fluoxetine, a generic version of the antidepressant Prozac, jumped from $9 to $69 in January 2019, an increase of $60 or 667 percent;
- Guanfacine, a generic treatment for high blood pressure and ADHD, jumped from $29 to $87 in February 2019, an increase of $58 or 204 percent; and
- Azacitidine, a generic version of the chemotherapy drug Vidaza, jumped from $105 to $210 in April 2019, an increase of $105 or 100 percent.

How much do prices for a generic or off-patent drug have to go up in order for a price hike to be referred to a state’s attorney general under the law?
The threshold for referral is an increase in the WAC, adjusted for inflation, of:

- 15 percent over the past year, or
- 40 percent over the past three years.

In addition, the dollar amount of the price increase must amount to at least $30 for a 30-day supply of the generic or off-patent drug. The $30 baseline will ensure that the percentages indicated in the threshold above won’t trigger attorney general action on drugs costing just pennies, but will instead be limited to increases with notable impacts on purchasers and consumers. To put the $30 baseline price increase for a 30-day supply in context, AARP reported that in 2017 the average annual cost of a generic drug, based on a basket of generic drugs widely used by older Americans, was $365 or approximately $30 a month per drug.*

How does this model act help consumers?
Manufacturers must, when possible, return revenue generated from excess price increases directly to consumers. If unable to pay consumers directly, manufacturers must return the excess revenue to the state to improve consumer access to prescription drugs.

What happens if a manufacturer refuses to sell the drug in the state?
Any manufacturer that withdraws a drug from sale within a state in response to this act must notify the state’s attorney general and board of pharmacy 180 days before doing so. The attorney general may assess a penalty on a manufacturer for withdrawing the drug from the state and use the funds – and advance warning – to ensure continued access to the drug for consumers in the state.
**Does this law address high launch prices of new drugs?**

No – while the price-gouging Model Act prohibits extreme price hikes, it does not address high launch prices. A separate NASHP model act, now in development, will give states tools to address high launch prices.