HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

February 29, 2024

Honorable Representative Donovan, Chair
House Health and Human Services Committee
Rhode Island State House
82 Smith St, Providence, RI 02903

HDA Letter of Opposition - H.7443

Dear Chair Donavan:

The Healthcare Distribution Alliance (HDA) would respectfully like to resurface our opposition to **H.7443, An Act Requiring Reference Based Pricing.** HDA is the vital link between the nation's pharmaceutical manufacturers and more than 360,000 pharmacies and other healthcare settings nationwide. An estimated 95% of US prescription drugs are handled by our members, who work around the clock to save the US Healthcare System billions annually through efficient management of drug supply chain logistics. In Rhode Island, our members serve over 800 customers (hospitals, pharmacies, and more).

Distributors are unlike any other supply chain participants – their core business **does not involve manufacturing, marketing, prescribing or dispensing medicines, and they do not set the Wholesale Acquisition Cost (WAC) list price of prescription drugs, influence prescribing patterns or determine patient-benefit design.** Rather, wholesale distributors are the logistics experts within the supply chain who ensure that drugs and other healthcare products are delivered in the most safe and efficient manner possible. Ensuring that the pharmaceutical supply chain remains stable, resilient, and secure is a top priority of our members, and to that end **we respectfully oppose H.7443.**

- **Inaccurate Inclusion of Distributors**

  HDA's greatest concern is the inclusion of distributors in the enforcement and penalties outlined in Sections 21-38-7 and 21-38-8. These sections misconstrue the roles of manufacturers and distributors and would inappropriately hold distributors responsible for manufacturer actions and responsibilities.

  Stating that it would be a violation of a manufacturer **or a distributor** to withdraw a drug due to MFP rate limits, and that both manufacturers and distributors would face fines of $500,000 for violations, puts distributors at risk for being penalized for manufacturer actions. Manufacturers- not distributors- set drug list prices, or Wholesale Acquisition Cost

(WAC), so a distributor cannot "negotiate in good faith" as the measure would require. Additionally, manufacturers and not distributors bring drugs to market, so if a manufacturer withdrew a drug from the market to avoid setting the list price of that drug at the MFP rate, a distributor cannot distribute it, and therefore should not face the risk of a fine. Finally, while a manufacturer might face a fine for one product, distributors work with over 1,500 manufacturers, distributing 95% of all products, so could face dipropionate and exorbitant fees. **We respectfully request that distributors be struck from these sections:**

21-38-7 Enforcement (Lines 10-14)

Each violation of this chapter shall be subject to a fine of one thousand dollars ($1,000). Every individual transaction in violation of § 21-38-3 is determined to be a separate violation. The attorney general is authorized to enforce the provisions of this statute. The refusal of a manufacturer ~~or distributor~~ to negotiate in good faith as described in § 21-38-8(d) shall be a valid affirmative defense in any enforcement action brought under this chapter.

21-38-8 Prohibition on withdrawal of referenced drugs for sale

(a) It shall be a violation of this chapter for any manufacturer ~~or distributor~~ of a referenced drug to withdraw that drug from sale or distribution within this state for the purpose of avoiding the impact of the rate limitations set forth in § 21-38-3.

(b) Any manufacturer that intends to withdraw a referenced drug from sale or distribution from within the state shall provide a notice of withdrawal in writing to the insurance commissioner and to the attorney general one hundred eight (180) days prior to such withdrawal.

(c) The insurance commissioner shall assess a penalty on any manufacturer ~~or distributor~~ that it determines has withdrawn a referenced drug from distribution or sale in the state in violation of subsection (a) or (b) of this section. With respect to each referenced drug for which the insurance commissioner has determined the manufacturer ~~or distributor~~ has withdrawn from the market, the penalty shall be equal to: (1) Five hundred thousand dollars ($500,000); or (2) The amount of annual savings determined by the insurance commissioner as described in § 21-38-6, whichever is greater.

(d) It shall be a violation of this chapter for any manufacturer ~~or distributor~~ of a referenced drug to refuse to negotiate in good faith with any payor or seller of prescription drugs a price that is within the referenced rate as determined in § 21-38-2.

(e) The insurance commissioner shall assess a penalty on any manufacturer ~~or distributor~~ that it determines has failed to negotiate in good faith in violation of § 21-38-7. With respect to each referenced drug for which the insurance commissioner has determined the manufacturer ~~or distributor~~ has failed to negotiate in good faith, the penalty shall be equal to: (1) Five hundred thousand dollars ($500,000); or (2) The amount of annual savings determined by the insurance commissioner as described in § 21-38-6, whichever is greater.

- **Supply Chain Concerns of a State-Level MFP**

H.7443 seeks to implement a state-level policy mirroring Medicare's Maximum Fair Price (MFP) at a time when the federal policy has not yet been fully determined or implemented. Considering such state-level policies during a time in which the industry is already undergoing fundamental and undefined drug policy changes at the federal level would have a severely damaging impact on the overall pharmaceutical supply chain. For example, CMS is still undergoing rulemaking regarding how to effectuate the Inflation Reduction Act's Market Fair Price, including establishing operational models that protect efficiency, accuracy, and program integrity. Creating a patchwork of state policies and pricing metrics for a variety of pharmaceutical products while a myriad of issues is still being resolved in advance of the federal roll out of the program would drastically increase overall costs in the supply chain and create unpredictability in the marketplace as a whole. HDA believes that states should take time to fully realize the impact of federal policy changes before seeking to add additional complications to the marketplace, in order to ensure that Rhode Island's patients maintain timely access to essential medications, and we strongly recommend that these measures not be advanced at this time.

Additionally, it is important to note that while the MFP represents the most that Medicare will pay for a drug, it does not change the national "list price" of drugs sold in the U.S. Reductions in price to CMS will likely be achieved through rebates paid to Medicare. Applying a state-level price ceiling does not adequately reflect how prescription drugs are bought and paid for in the U.S. and would place a cap on in-state purchases but not out-of-state purchases, ultimately limiting the ability of pharmacies, clinics or other points of care to recoup costs for administering or dispensing these products, which could result in sites of care being unable to stock these medications.

In conclusion, for the security of the supply chain and to ensure Rhode Island patients retain access to the drugs they need where and when they need them, HDA respectfully urges the Committee not advance H.7443 at this juncture. However, if H.7443 is advanced, we would further request that distributors be struck from Sections 21-38-7 and 21-38-8, per the redlines above.

HDA would like to thank you for your consideration of our concerns, and please contact Kelly Memphis at kmemphis@hda.org for further discussion.

Sincerely,

Kelly Memphis

Kelly Memphis

Director, State Government Affairs
Healthcare Distribution Alliance