



Healthcare Distribution Alliance

PATIENTS MOVE US.

March 10, 2021

Representative Bronna Kahle, Chair
House Health Policy Committee
Room 352, House Appropriations
State Capitol Building
Lansing, MI 48933

Re: HDA Letter, House Bill 4347

Dear Chairwoman Kahle and Members of the Health Policy Committee,

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing primary healthcare wholesale distributors, I would like to thank you for the opportunity to provide HDA's position on House Bill (HB) 4347. HDA believes that it is critical that any legislative proposal considered in Michigan, or other states, accurately reflect the roles and responsibilities of the healthcare distribution industry. Respectfully, HDA requests that the definition of pharmaceutical manufacturer in HB 4347 be amended to more accurately achieve the intent of the legislation.

HDA represents the nation's healthcare wholesale distributors who work around-the-clock to safely and efficiently distribute pharmaceutical and medical products to pharmacies, hospitals and other healthcare providers nationwide. In their role as distributors, wholesalers do not conduct research, manufacture, promote or prescribe medications, nor do they influence prescribing patterns, the demand for specific products or patient-benefit designs. Their primary role is to ensure that medicines travel from manufacturers to dispensing locations safely, securely and efficiently. Approximately 93 percent of all pharmaceuticals utilized in the United States arrive at their ultimate point of dispensing or administration from a primary wholesale distributor.

In HB 4347, the definition of pharmaceutical manufacturer is as follows:

"drug manufacturer" is a person who prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and who supplies, distributes, sells, offers for sale, barter, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing.

In their role as logistics experts in the supply chain, wholesale distributors can engage in packaging, repackaging, labeling, and distributing the drugs and medical products that providers and pharmacies receive based on the specific need of the provider location. However, these activities do not constitute drug manufacturing, and engaging in these activities does not make wholesale distributors drug manufacturers. Respectfully, HDA would ask that the legislation use the federal definition in Centers for Medicare & Medicaid Services (CMS) statute 42 CFR 447.502, provided below:

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) For authorized generic products, the term “manufacturer” will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term “manufacturer” will also include the entity under whose own label or trade name the product will be distributed.

HDA supports the state’s efforts to address drug pricing and believes that these amendments will help HB 4347 reflect the various components of the supply chain accurately. I appreciate the opportunity to share these concerns with you and look forward to an open dialogue on this topic throughout the legislative session. Please contact Roxy Kozycky at (703) 885-0229 or rkozyckyj@hda.org, if you have any questions or would like to discuss this issue further.

Sincerely,



Roxolana Kozycky
Director, State Government Affairs
Healthcare Distribution Alliance