Michigan Manufacturers Association

MEMO

TO:	Michigan House Health Policy Committee Members
FROM:	David Q. Worthams, Director of Human Resource Policy
DATE:	3/17/2021
Re:	HB 4357 – 58 Opposition

On behalf of the members of the Michigan Manufacturers Association (MMA), all of whom strive to provide the best health care benefits for our employees, I write to express our concerns with House Bills 4357(Roth) and 4358(Hammoud) which would negatively impact our members' ability to help patients access advanced pharmaceuticals.

HB 4357 limits gifts from pharmaceutical companies as they market and promote their products to physicians and others who write prescriptions for patients. It further establishes that pharmaceutical representatives disclose to prescribers the cost of a drug. While the intent is to increase oversight of the marketing activities of pharmaceutical manufacturers, proponents of the bill fail to mention that many of the disclosures and restrictions are already contained in federal regulation regarding the sale of pharmaceuticals.

Title 21, Part 99, Subpart F of the Code of Federal Regulations requires that a drug manufacturer who shares information with physicians must maintain records that allow manufacturers to provide to the FDA all of the information required by HB 4357 and more[1]. This information must identify the person, by name, who received information about a product, semiannually provide a list of all articles and reference publications used to generate the information shared, provide a list of all pharmacy benefit managers, health insurance issuers, federal and state government agencies, and group health plans that receive the information, as well as providing the FDA with all records needed to allow corrective action to be taken when necessary.

Further, while there are 11 states that have gift bans, there is no standard level of ban or reporting in those states. Adding Michigan to that list will mean there will be 12 different standards that manufacturers will have to follow, making an already complex regulatory puzzle even more burdensome. How can a manufacturer successfully deal with the administrative reporting nightmare of 12 different standards to follow?

Some will suggest that the Code of Professional Conduct that the Pharmaceutical Research and Manufacturers of America (PhARMA) has established with their members is followed on a voluntary basis only. It is important for members to keep in mind that ethical relationships with health care

[1] Code of Federal Regulations Title 21 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=99&showFR=1&subpartNode=21:1.0.1.1.33.6)

professionals and between health care professionals is critical to the mission that all members of the industry follow – to help patients achieve better health by developing and marketing new medicines.[2]

Regarding HB 4358, we acknowledge that prescription drug costs account for approximately 23% of total health care costs in the United States. This is a dramatic increase over the last 17 years when, in 2006, the amount was 6%. Drug prices are outpacing the Consumer Price Index by 150% over the last decade alone. As purchasers of health care insurance for our employees, we appreciate that the work various health plans undertake to control health prices and formulary management protocols is important in that effort. Aside from controlling health care costs, these protocols also ensure that covered prescription drugs are safe, effective, and affordable. HB 4358 restricts the ability of health plans to make formulary changes during the year.

We concur with many of our colleagues who point out that when changes to formulary protocols are made, they are done based on evidence-based guidelines, input from physicians and pharmacists, availability of new drugs entering the market (both brand name and generic), and overall levels of available doses to the public. Additionally, the Centers for Medicare & Medicaid Services (CMS) require health plans to have appropriate drug utilization management programs intended to reduce costs when medically appropriate and those programs must assist in preventing over-utilization or under-utilization of prescribed drugs.[3]

We firmly believe that limitations on formulary changes during a policy term would severely restrict a health plan's ability to manage the covered pharmaceuticals in a cost-effective and consumer-focused way.

Based on these reasons, we urge committee members to oppose HB 4357-58.

[2] PhRMA Code on Interactions with Health Care Professionals (https://www.phrma.org/en/Codes-and-guidelines/Code-on-Interactions-with-Health-Care-Professionals)
[3] Improving Drug Utilization Review Control in Part D (https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxutilization)