STATEMENT

PhRMA
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February 26, 2020

House Health & Government Operations Committee – Maryland
HB 1119 and HB 664 – Pharmacists – Therapeutic Substitution
OPPOSED

Position: PhRMA opposes Maryland HB 1119 and HB 664 because they modify existing law to permit substitution of provider prescribed drugs with drugs in the same therapeutic class but with different chemical makeups. PhRMA is concerned that this could be harmful to patient health, add costs to the health care system, and undermine the prescriber-patient relationship.

Therapeutic substitution can be harmful to patient health

Therapeutic substitution is very different than commonly practiced generic substitution. Maryland already allows for generic substitution. PhRMA believes in the appropriate use of generic drugs (FDA AB rated drugs). Generics are copies of drugs that have reached the end of their patent life after being developed by research-based pharmaceutical and biotechnology companies. For many patients, generic drugs can provide the appropriate therapy.

Therapeutic substitution assumes that each drug product in the same class is an identical product, whether brand or generic. However, therapeutic class may have many different prescription drugs to treat a similar clinical indication. Drugs in the same class will have significant differences in their chemical formulas and mechanism of action to provide the drug's benefits. Switching drugs in a class could pose significant danger to patient health if there are possible side effects or a patient has additional health conditions.

Many patients suffer from multiple conditions that are being managed by prescription drugs; therefore, switching to another medication within the same therapeutic class could upset the stability of their ongoing treatment plan. Only the treating provider has the full clinical understanding of the patient's current health and potential comorbidities, not the pharmacist at the pharmacy counter. The treatment plan is a result of the physician or other provider's knowledge of possible drug interactions, drug-disease interactions, and the patient's concurrent illnesses. A change to any element of the therapy plan could have adverse results on patient health.

Patients often fill their prescriptions at more than one pharmacy. This means that a pharmacist does not have the complete picture of the medication that a patient is taking making a therapeutic substitution even more of a safety risk.

Therapeutic substitution may add unintended costs to the system

Appropriate prescription drug therapy enhances the quality and cost-effectiveness of medical treatment. A pharmacist's decision for therapeutic substitution could lead to unintended patient health

outcomes, resulting in additional health care expenditures such as added provider visits or hospitalizations.

Therapeutic substitution is cost driven, not patient driven, and jeopardizes patient safety. A patient may be given an entirely different drug each time they refill their prescription depending on the cost of the medications on the date of refill. And, each medication within a therapeutic category has its own unique clinical and chemical characteristics; consequently, forcing patients to switch between medications can trigger drug interactions, side effects, and treatment failures—all of which could harm patients and add costs to the medical system.

Maintaining the good health of Maryland residents is of paramount importance. Allowing pharmacists to dispense medication not prescribed by a treating physician or nurse practitioner for cost purposes alone is not good for patient safety, it's bad policy.

Therapeutic substitutions undermine the prescriber-patient relationship

The provider-patient relationship, more specifically, the provider relationship with their patient is a critical issue in health-care markets and a major component of quality medical service delivery.

Allowing pharmacists to dispense medications not prescribed by a treating provider represents an unwelcome and dangerous development for patients in the state. The practice of pharmacy is not the practice of medicine, and the proposed legislation would blur what are currently clear lines. And unfortunately, it also calls into question the likelihood of conflict of interests associated with the business of pharmacy and the best needs of patients. Moreover, passage of the bill could have the unintended consequence of generating additional costs to the health care system in the form of adverse patient outcomes that create remediation expenses or in terms of required additional physician visits if the substituted medication has adverse side effects or is ineffective.

For the above reasons, PhRMA **opposes HB 1119 and HB 664** and respectfully asks for an unfavorable vote.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone. In Maryland, the biopharmaceutical industry directly employs 30,550 individuals and generates a total economic output of over $33.8 billion per years while contributing over $2.3 billion in state and federal taxes annually. Additionally, the industry rebates more than $635 million back to the federal and state governments through Medicaid prescription drug rebates according to CMS data analyzed by Menges Group.