

BRIAN E. FROSH
Attorney General

WILLIAM D. GRUHN
Chief
Consumer Protection Division

ELIZABETH F. HARRIS
Chief Deputy Attorney General



CAROLYN QUATTROCKI
Deputy Attorney General

STATE OF MARYLAND
OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

Writer's Direct Fax No.
(410) 576-6571

Writer's Direct Dial No.
(410) 576-6515

Writer's Direct Email:
pocannon@oag.state.md.us

February 16, 2021

To: The Honorable Paul G. Pinsky
Chair, Education, Health, and Environmental Affairs Committee

From: Office of the Attorney General's Health Education and Advocacy Unit

Re: Senate Bill 537 (Pharmacists - Required Notification and Authorized Substitution Lower-Cost Drug or Device Product): Oppose

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) opposes Senate Bill 537 which would allow pharmacist substitutions, without prescriber authorization, well beyond the scope of substitutions currently allowed without prescriber authorization. We oppose pharmacist substitutions without prescriber authorization like those the bill would allow because such substitutions lack reliable, authoritative support from U.S. Food and Drug Administration (FDA), would constitute the practice of medicine and could be financially driven.

We believe the current law strikes the right balance between patient protection and cost containment by allowing a pharmacist to substitute a lower cost, specifically defined generic for a brand drug if the prescriber did not order 'dispense as written'. The specifically defined generics are those "[r]ecognized in the [FDA]'s current list of approved drug or device products with therapeutic equivalence evaluations". Md. Code Ann. Health Occ. § 12-504(d)(2)(i). In other words, the FDA has determined the brand drug and the specifically defined generic are the same for the prescribed purpose.

The FDA has not determined the therapeutic equivalence of brand drugs that would be substituted for one another, without prescriber authorization, as proposed in the bill. We are not aware of any other reliable authority that could serve as an acceptable substitute for prescriber authorization.

We agree with the sponsor that increasing the pharmacist's required disclosures

pursuant to Md. Code Ann. Health Occ. § 12-504(b)(1) could benefit consumers, but must oppose the bill unless the proposed changes to subpart (d) of the statute are deleted. We are unable to propose alternative amendments adequate to mitigate our concerns, despite our agreement with the bill's apparent goals of reducing prescription drug costs and improving patient medication adherence.

For these reasons, we ask the Committee for an unfavorable report.

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