

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:
pocconnor@oag.state.md.us

February 3, 2021

To: The Honorable Shane E. Pendergrass
Chair, Health and Government Operations Committee

From: Patricia F. O'Connor, Health Education and Advocacy Unit

Re: House Bill 429 (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 House Bill 429 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 have discussed our concerns with the bill's sponsor, and while we agree with the sponsor's goals of reducing prescription drug costs and improving patient medication adherence, we cannot propose alternative amendments adequate to mitigate our concerns.

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

cc: Sponsor