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TO: The Honorable Joseline A. Pena-Melnyk, Chair
Members, House Health and Government Operations Committee
Chair, House Health and Government Operations Committee (Maryland Department of Health)

FROM: Pamela Metz Kasemeyer
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DATE: January 31, 2024

RE: **OPPOSE** – House Bill 127 – *Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment*

On behalf of the Maryland State Medical Society and the Maryland Chapter of the American Academy of Pediatrics, we submit this letter of **opposition** for House Bill 127.

House Bill 127 establishes a Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program, which authorizes a licensed pharmacist to prescribe and dispense nPEP under certain circumstances as well as authorize a licensed health care provider to dispense nPEP and delegate the dispensing of nPEP to an employee or volunteer of a “private or public entity” under a written agreement.

While there is appreciation for the intent of the legislation, which is to facilitate access to post-exposure prophylaxis HIV medications in order to enhance HIV prevention, there are a number of significant concerns with this proposal, some of which may have unintended consequences and therefore would undermine the presumed objectives of the legislation.

The inclusion of post-exposure prophylaxis in the medications that a pharmacist is authorized to dispense without a prescription is of concern. The recommended medical care, counselling, and other services that are critical to be provided post-exposure are not within the scope of practice of a pharmacist. Similarly, the provision that would authorize an employee or volunteer under a written agreement to dispense nPEP is also of significant concern.

nPEP medications are not always safe or well-tolerated by individuals. They can cause kidney and liver issues and are also contraindicated in some cases depending on an individual’s current medication regime. nPEP can only be safely dispensed after an individual has had baseline laboratory

tests as well as clinical screening to determine if the medications are appropriate or whether modifications are indicated. Pharmacists are not normally permitted under their scope of practice to order laboratory tests without a prescription from a prescriber and are not trained to “screen” patients in the way that physicians are. The same would be true of employees and volunteers regardless of a written agreement.

In addition, ongoing counselling and follow-up care is essential to effectively address not only the impacts of potential HIV exposure but to also ensure there are not unintended health consequences from the medication. nPEP is taken for 30 days, it is not a one-time medication. Follow up care, including testing for unintended clinical impact is critical.

Finally, there is also a concern about patient safety as there are no existing mechanisms to track prescriptions that are not controlled dangerous substances and, therefore, there is nothing to prevent a patient from obtaining nPEP from multiple pharmacies as there is no requirement to monitor or share this information.

The above-named organizations appreciate the intent and objectives of the proposed standing order concept. It is analogous to the standing order of opioid reversal drugs, such as Naloxone. However, the dispensing of nPEP is significantly more complicated, clinically, than opioid reversal drugs and could cause unintended consequences for the individuals who would receive nPEP without the necessary screening and laboratory tests. MedChi and MDAAP will continue to work with the Department to identify mechanisms for expanding access to nPEP, when appropriate, but are unable to support the bill, as introduced, unless the bill can be amended to address the HIV testing, prescribing, and dispensing issues raised by ensuring a defined and direct relationship with a physician(s), analogous to the therapy management contract, so that there is assurance that the appropriate authority, clinical expertise, and standard of care is provided to individuals to effectively enhance HIV prevention. An unfavorable report is requested.

For more information call:

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