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Testimony in Support of Senate Bill 440 (2020)

Pharmacists - Aids for the Cessation of Tobacco Product Use
Before the Education, Health, and Environmental Affairs Committee: February 13, 2020

Senate Bill 440 authorizes a pharmacist to prescribe and dispense medications approved by the Food and Drug Administration (FDA) as an aid for the cessation of the use of tobacco products. The bill requires the Board of Pharmacy to adopt regulations that will establish the standard procedures pharmacists must follow when prescribing and dispensing tobacco cessation products. One such regulation will require a pharmacist to, after prescribing or dispensing a tobacco cessation product, refer the patient to his/her primary care practitioner for treatment *and* provide the patient with information on the importance of seeing the patient's primary care practitioner. The bill also requires the Maryland Medical Assistance Program and Maryland Children's Health Program to provide coverage for services pharmacists render to enrollees.

Other States Allow Pharmacists to Prescribe and Dispense Tobacco Cessation Medications

Pharmacist authority to prescribe and dispense medications approved by the FDA as an aid for the cessation of the use of tobacco products is not new. In 2004, New Mexico was the first state to give pharmacists this authority. Currently, pharmacists have this authority in 10 states – AZ[1], AR[2], CA[3], NM[4], ID,[5] IN[6], IA[7], CO[8], ME[9], and OR.[10] While nine of the states passed this law in 2016 or later making it too soon to determine the impact on cessation rates, New Mexico, which adopted the law in 2004, now continually experiences an adult smoking rate below the national average. The provisions in all 10 states are similar to those in SB440: pharmacists prescribe and dispense but do not diagnose; standard procedures that pharmacists must follow; regulation by the state Board of Pharmacy; requirements for recording the

[1] A.R.S. § 32-1979.03.
[2] A.C.A. § 17-92-101.
[3] West's Ann.Cal.Bus. & Prof.Code § 4052.9.
[4] N.M. Board of Pharmacy Regulation 16.19.26.
[5] Idaho Code Ann. 54-1733E.
[6] Indiana Code Ann. 16-19-4-11.
[7] I.C.A. § 155A.46.
[8] Colorado State Board of Pharmacy Approved Statewide Protocol for Dispensing Tobacco Cessation Products. 2016. Available at https://www.sos.state.co.us/CCR/Upload/AGORequest/AdoptedRules22016-00628.pdf. Accessed 2-25-19.
[9] 32 M.R.S.A. § 13702-A.
[10] Oregon Rev. Stat. 689.645.

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medication dispensed and patient follow-up with a primary care physician, and; completion of a training program. In 2019, 15 states introduced similar legislation.[11]

This Bill Will Allow Pharmacists to Complement the Physician-Patient Relationship and Improve Access

Granting pharmacists the authority to prescribe smoking cessation medications will complement, rather than interfere with, the physician-patient relationship. Physician's are extremely busy and research suggests that smoking cessation is not always adequately addressed during primary care visits. In 2019, a study found many smokers did not receive *any* advice or support to quit smoking during a healthcare visit.[12] The study specifically looked at varying age groups and individuals with chronic diseases. Advice and support were highest among individuals 55 and older with chronic diseases while advice and support were lowest for healthy individuals aged 18 to 24.[13] Additionally, another study examined physicians' lack of engagement with smoking cessation and found that physicians do not routinely provide smoking cessation treatment to their patients "due to barriers such as frustration, negative attitudes towards patients who continue to smoke, and lack of experience with smoking cessation technique."[14] Similarly, 42% of U.S. physicians reported they believe discussing smoking cessation is too time-consuming, 39% reported their time with the patient is too limited, and 38% reported they do not believe it is effective.[15]

SB440 can fill this care gap and alleviate both patients and physicians from these issues by increasing access to these medications. If SB440 passes, physicians will no longer be required to do all of the heavy-lifting on smoking cessation efforts. SB440 would instead require the pharmacist to make a referral to the primary care physician immediately after dispensing the prescription. As a result, physicians would still be involved in patient care and able to monitor treatment, however, they would no longer be required to meet with patients for them to attain these prescriptions.

More importantly, patient access would significantly increase as patients wanting to quit could acquire these medications much quicker. As this process currently stands, patients must

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[11] National Alliance of State Pharmacy Associations. Youth Tobacco Use on the Rise; Access to Cessation Resources Critical. Available at https://naspa.us/2019/02/youth-tobacco-use-on-the-rise-access-to-cessation-resources-critical/. Accessed 2-18-19.

[12] Hedman L, Katsaounou PA, Filippidis FT, et al. Receiving support to quit smoking and quit attempts among smokers with and without smoking related diseases. *Tobacco Induced Diseases*. 2019. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6661851/. Accessed 1-24-2020.

[13] *Id.*

[14] Eam, V., Risor, M., Spigt, M., et al. Why do physicians lack engagement with smoking cessation treatment in their COPD patients? A multinational qualitative study. *NPJ Prim Care Respir Med.* 2017. Available at https://www.ncbi.nlm.nih.gov/pubmed/28646217/. Accessed 2-4-2020.

[15] MDQuit.org. Available at https://mdquit.org/providers/physicians. Accessed 2-4-2020.

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first make an appointment with their physician or nurse practitioner prior to obtaining a prescription. This timeframe can last anywhere from weeks to months. During this period, those motivations and desires could change by the time their appointment comes. Additionally, if a person is contemplating quitting, they may be more likely to attempt cessation if they were able to acquire the means of doing so by merely walking into a pharmacy rather than waiting weeks to months for an appointment with a physician. SB440 aims to directly achieve this: permitting patients in most circumstances to acquire cessation prescriptions when they want them. In fact, many smokers may walk into a pharmacy debating whether they should buy more cigarettes *or* buy NRT products or cessation medications. SB440 allows real-time access to cessation products so that smokers considering which product to buy have *a choice*.

Smoking Cessation Medications are Safe

Use of cessation medications is appropriate for most adult smokers except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness, like pregnant women.[16] Nicotine replacement therapy (NRT), which includes gum, lozenges, the patch, nasal spray, and inhalers, are well-established, safe and effective means of cessation. NRT delivers controlled, therapeutic doses of nicotine to gradually lower a person's dependence on nicotine and is the only over-the-counter smoking cessation option that is FDA approved.[17]

Unlike NRT, the tobacco cessation drugs, varenicline (commonly known as Chantix) and bupropion (commonly known as Zyban or Wellbutrin) require a prescription. The Food and Drug Administration (FDA) once required black box warnings on the drug labels to signify that there was reasonable evidence of an association of serious adverse effects or life-threatening risks with taking the prescription medication. Importantly, the requirement was removed in 2016 after FDA review.[18] The FDA concluded that ***the results of clinical trials "confirm that the benefits of stopping smoking outweigh the risks of these medicines***."[19] In fact, research indicated that the

[16] US Public Health Service. Treating tobacco use and dependence: 2008 update. Clinical practice guideline. Rockville, MD: US Department of Health and Human Services, US Public Health Service; 2008. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html. Accessed 2-18-19.

[17] American Cancer Society. Guide to quitting smoking. https://www.valdosta.edu/administration/finance-admin/human-resources/documents/acs-quit-smoking-guide.pdf. Published February 6, 2014. Accessed 2-10-20.

[18] FDA Drug Safety Communication..." FDA. 2018. Available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-revises-description-mental-health-side-effects-stop-smoking. Accessed 2-3-20.

[19] *Id.*

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adverse events associated with these drugs, which led to the black box warnings, are no greater than that of the nicotine patch.[20]

While these medications still have side effects, like any drug, they are no longer considered to be dangerous, as initially thought. The risks of side effects are most common in individuals with preexisting conditions, such as depression and anxiety. These conditions, however, can adequately be screened for by pharmacists prior to administering and tailoring a proper treatment for a particular patient. Additionally, because SB440 requires that each case be referred to a physician following the administration of the prescription, physicians would still be involved in the therapy and able to aid pharmacists in detecting potential issues.

Conclusion

Pharmacist prescription and dispensing authority is not a new concept in Maryland. As recently as 2017, pharmacists were given this authority to prescribe birth control – a more complicated medicine than smoking cessation aids. Additionally, this authority is not new across the country. Many states in response to public health issues have given pharmacists the ability to prescribe not just smoking cessation aids, but also contraceptives, immunizations/vaccines, naloxone, travel shots, and others. Pharmacist authority to prescribe and dispense medications approved by the FDA as an aid for smoking cessation is a well-studied practice that is gaining momentum. Black box warnings have been removed for the prescription-only medications as they are no longer considered to have serious, adverse consequences. Pharmacists are properly trained to prescribe these medications and have been safely doing so for almost 16 years in New Mexico. Pharmacists are accessible, knowledgeable, and members of a trusted community healthcare providers who have all of the tools necessary to assist smokers in quitting. Passing SB440 would significantly increase patient access and increase the likelihood of successful cessation.

This testimony is submitted on behalf of the Public Health Law Clinic at the University of Maryland Carey School of Law and not by the School of Law, the University of Maryland, Baltimore, or the University of Maryland System.

[20] Leischow, Scott J. "Increasing Smoking Cessation in the United States: Expanding the Availability of Over-the-Counter Medications." Journal of American Medical Association. 2019. Available at https://mfprac.com/web2019/07literature/literature/Misc/SmokingCessation_Leischow.pdf. Accessed 2-4-20.

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