

UMLaw_Carter_FAV_SB440

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Position: FAV

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 – AZ¹, AR², CA³, NM⁴, ID,⁵ IN⁶, IA⁷, CO⁸, ME⁹, 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.

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. Physicians 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

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.

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.*

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/web2019/07/literature/literature/Misc/SmokingCessation_Leischow.pdf. Accessed 2-4-20.

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UMB_DebDewitt_FAV_SB0440

Uploaded by: Dewitt, Deb

Position: FAV



February 13, 2020

The Honorable Paul G. Pinsky
Chair, Senate Education, Health & Environmental Committee
2 West Miller Senate Office Building
Annapolis, MD 21401

Support: SB 440 Pharmacists – Aids for the Cessation of Tobacco Product Use

Dear Chairman Pinsky and Members of the Committee:

Promoting and supporting smoking cessation programs is an important priority for policy makers, healthcare professionals, academics, and government officials. On behalf of the leadership from the schools of pharmacy, we urge your support for SB 440 Pharmacists – Aids for the Cessation of Tobacco Product Use. This bill would authorize a pharmacist, who meets specified requirements, to prescribe and dispense medications approved by the U.S. Food and Drug Administration (FDA) as an aid for the cessation of tobacco products.

Lung cancer is still the leading cause of cancer death in the United States - with only an 18.6 percent five-year survival rate¹. Prevention of cigarette smoking and help for those wishing to quit can yield enormous health benefits for populations and individuals. Clearly, more effort remains to be done to reduce the morbidity and mortality of this disease. Likewise, asthma is a serious health issue for our nation and state. Asthma associated from secondhand smoke costs the health system \$80 billion annually and is responsible for 1.7 million emergency department visits and more than 1.5 million outpatient hospital visits annually. **Pharmacists can play a much wider role in reducing the prevalence of smoking and aid in the reduction of lung cancer, asthma, and respiratory illnesses.**

Three decades ago, US Surgeon General C. Everett Koop, MD stated that, “Encouraging smoking cessation is one of the most effective and cost effective things that doctors and other health professionals can do to improve health and prolong their patients' lives.”² Recognizing the role of the pharmacists in smoking cessation efforts, the Centers for Disease Prevention and Control (CDC) created a toolbox with resources specifically designed for pharmacists to use with patients seeking information on smoking cessation.

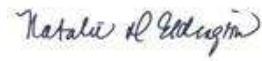
In 2017, to spur adoption of CDC policy, CMS’s Center for Medicaid and CHIP Services (CMCS) issued an Informational Bulletin encouraging states to expand the scope of pharmacy practice as a way of fostering immediate access to certain drugs. Although CMCS noted these practices are optional for states, they stressed [pharmacy scope of practice expansion] can “facilitate easier access to medically necessary and time-sensitive drugs for Medicaid beneficiaries.”³ In the bulletin, CMCS specifically cited tobacco cessation products.

Smoking cessation medications, including nicotine replacement therapies (NRTs) and non-nicotine replacement therapies (NNRTs), have been shown to increase tobacco abstinence rates. These medications are currently indicated for smoking cessation, and pharmacists are well educated to select the appropriate medication therapies and subsequently monitoring for therapeutic efficacy and adverse events.

Pharmacists are well positioned within the community to help patients initiate attempts to quit smoking or complement the cessation efforts initiated by other providers. Stopping smoking has substantial immediate and long-term health benefits for smokers of all ages. Currently 12 states have similar statutes or regulations for pharmacist to prescribe and dispense smoking cessation aids.

Thank you for your consideration of our request. We urge a favorable outcome.

Sincerely,



Natalie D. Eddington, PhD, FAAPS, FCP
Dean and Professor
Univ of Maryland School of Pharmacy



Anne Lin, PharmD, FNAP
Dean and Professor
Notre Dame of Maryland University



Rondall E. Allen, BS, PharmD
Dean and Professor
Univ of Maryland Eastern Shore

cc: The Honorable Antonio Hayes

¹ American Society of Clinical Oncology (ASCO). Survivor Rates. Retrieved from <https://www.cancer.net/survivorship> Jan 2020

² U.S. Department of Health and Human Services. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1982

³ US Preventative Service Task Force. Recommendations for Primary Care Practice. 2017; <https://www.uspreventiveservicestaskforce.org/Page/Name/recommendations/>.

³ CMS Center for Medicaid and CHIP Services. (2017, January 17). *CMCS Informational Bulletin*. Retrieved from <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf>

BCA_SB440_FAV

Uploaded by: Green, Kamala

Position: FAV



BERNARD C. "JACK" YOUNG
MAYOR

*Office of Government Relations
88 State Circle
Annapolis, Maryland 21401*

SB 440

February 13, 2020

TO: Members of the Education, Health, and Environmental Affairs and Finance
FROM: Nicholas Blendy, Deputy Director, Mayor's Office of Government Relations
RE: Senate Bill 440 – Pharmacists – Aids for the Cessation of Tobacco Product Use
POSITION: SUPPORT

Chair Pinsky, Vice Chair Kagan, and members of the committee, please be advised that the Baltimore City Administration (BCA) **supports** Senate Bill (SB) 440, which authorizes a pharmacist who meets the requirements of certain regulations to prescribe and dispense aids for the cessation of the use of tobacco products.

Tobacco use is the leading preventable cause of death in the United States, and is routinely sold in pharmacies.¹ Although smoking rates have declined in the United States, tobacco use still causes about 480,000 deaths each year. In light of the health consequences, seven in ten current smokers want to quit. Evidence suggests that quit attempts are most successful when supported by evidence-based treatments, including pharmaceutical aids and counseling services.

The United States Preventive Services Task Force (USPSTF), a panel of experts in prevention and evidence-based medicine recommends interventions based on a rigorous assessment of peer-reviewed evidence, found that a combination of pharmacotherapy and behavioral interventions was most effective in assisting individuals to quit smoking.² The suggested pharmacotherapy is Nicotine Replacement Therapy (NRT). The purpose of NRT is to aid in smoking cessation by replacing the use of tobacco products, and with proper use and a tapering regime.

Pharmacists are well-positioned and currently an untapped resource to initiate treatment and support individuals throughout the quitting process. Since pharmacists are located in

¹ Apollonio, DE; Pimentel, (2019). Placement and sales of tobacco products and nicotine replacement therapy in tobacco-free and tobacco-selling pharmacies in Northern California: an observational study.

² 2017, Tobacco Control Network; "Access to Tobacco Cessation Medication through Pharmacists."

communities and can typically be seen without appointments, they are often more readily available than other healthcare providers and can respond quickly to modify interventions. In a 2007 review, researchers concluded that early studies “collectively demonstrate the positive impact that pharmacists can have on increasing smoking cessation.”

States like New Mexico, California, Idaho, and Oregon have already expressly authorized pharmacists to provide a tiered approach to assist smokers in quitting. This includes brief advice with nicotine replacement therapy and more intensive advice plus nicotine replacement therapy. Smoking cessation is a dynamic process that smokers move through in the determination to quit smoking. Pharmacists are trained to assess the readiness of the smoker to quit smoking. They can provide information ranging from the health benefits of quitting to the most appropriate cessation tools. It would be advantageous and cost effective to cessation resources at the point of sale of other commonly utilized medications.³

In Baltimore, there are 20.9 stores that sell tobacco per 10,000 residents. There are 5.9 deaths per 10,000 residents due to lung cancer. Lung cancer is the most prevalent cause of cancer death in Baltimore City. These startling statistics drive the need to create innovative strategies to assist Baltimore City residents in their efforts to quit smoking. Maryland has leveraged a variety of strategies to ensure its citizens that want to quit smoking have access to effective, evidenced-based smoking cessation options. This bill increases access to tobacco cessation services by leveraging pharmacists through collaborative practice agreements and statewide protocol. With 50 local pharmacies and 17 located in hospitals, Baltimore City would benefit from the implementation of this bill.⁴

SB 440 represents an innovative health promotion strategy to educate residents and build capacity to reduce cancer mortality as well as the harmful effects of smoking. This bill will build on existing Baltimore City efforts to expand knowledge about the harmful effects of smoking and leverage resources for smoking cessation.

For the forgoing reasons, we respectfully request a **favorable** report on Senate Bill 440.

³ El Hajj, M. S., Kheir, N., Al Mulla, A. M., Al-Badriyeh, D., Al Kaddour, A., Mahfoud, Z. R., Salehi, M., ... Fanous, N. (2015). Assessing the effectiveness of a pharmacist-delivered smoking cessation program in the State of Qatar: study protocol for a randomized controlled trial. *Trials*, 16, 65. doi:10.1186/s13063-015-0570-z

⁴ Baltimore City Health Department Community Health Assessment 2017.

MPha_Horton_FAV_SB440

Uploaded by: Horton, Aliyah

Position: FAV



Date: February 13, 2020

To: The Honorable Paul G. Pinsky, Chair

From: Aliyah N. Horton, CAE, Executive Director, 240-688-7808

Cc: Members, Senate Education, Health and Environmental Affairs Committee

RE: SUPPORT SB 440-Pharmacists – Aids for the Cessation of Tobacco Product Use – Prescribing and Dispensing

The Maryland Pharmacists Association (MPhA) supports SB 440: Pharmacists – Aids for the Cessation of Tobacco Product Use – Prescribing and Dispensing.

MPhA founded in 1882 is the only state-wide professional society representing all practicing pharmacists in Maryland. Our mission is to strengthen the profession of pharmacy, advocate for all Maryland Pharmacists and promote excellence in pharmacy practice. In doing so, we prioritize and value the health and well-being of Maryland residents; safe and effective use of medications and health care devices; collaboration among health care professionals and organizations; professional competence and responsible legislation and regulations.

According to the Maryland Department of Health’s smoking data (2016), **7,500 adults in Maryland die each year due to tobacco-related causes and hundreds of thousands more suffer from tobacco-related diseases such as COPD, emphysema or cancers.**

2020 Surgeon General Report Supports Pharmacists Interventions for Tobacco Cessation

“Clinical interventions for smoking cessation are critical if we are to achieve our goal of eliminating the devastating effects of smoking on public health. Primary care physicians, nurses, **pharmacists**, and other providers in all medical disciplines and in all healthcare environments should take advantage of these opportunities to inform and encourage smokers to quit. Doing so could **enable half a million smokers to quit each year.**”¹

“Treating Tobacco Use and Dependence:

- Any level of treatment is beneficial, and more intensive and longer behavioral and pharmacologic treatment is generally better.
- Physicians, psychologists, pharmacists, dentists, nurses, and numerous other healthcare professionals can treat nicotine addiction in smokers. Thus, by extension, the various settings in which such professionals work represent appropriate venues for providing these services.
- Behavioral interventions and FDA-approved pharmacotherapies are effective for treating nicotine dependence. A combination of behavioral interventions and pharmacotherapy is the optimal treatment based on overwhelming scientific evidence, with superiority in efficacy over either intervention alone.”²

¹ Smoking Cessation: A Report of the Surgeon General, <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf> (accessed January 2020)

² IBID

Smoking Kills; Pharmacists Can Help

Smoking continues to be a serious public health problem in the United States. Not only do people who smoke have higher healthcare costs, an estimated 480,000 people die each year from smoking-related illness.³ With e-cigarette use on the rise, and data to show teen e-cig users are much more likely to start smoking cigarettes, tobacco use is a problem unlikely to go away soon.⁴

Pharmacists are highly accessible and ready to help people quit smoking. Pharmacists are available at convenient locations, for extended hours, and on weekends and pharmacy students are trained on tobacco cessation techniques. And research shows that pharmacist-provided tobacco cessation services are just as effective as those provided by other healthcare providers.⁵

Tobacco Cessation Aids are Safe and Effective

Quitting smoking is difficult but tobacco cessation aids, paired with counseling, can help. Research shows that patients who use a tobacco cessation medication are much more likely to quit. Recognizing the safety and efficacy of varenicline (Chantix) and bupropion (Zyban), the Food and Drug Administration (FDA) removed their labels' Black Box Warnings in 2016 – something never done before. The change was based on very strong research, the EAGLES study, which showed that varenicline and bupropion had a similar safety profile to that of over-the-counter nicotine replacement products.⁶

Give Maryland Residents Access to Important Tobacco Cessation Services

Pharmacists are a great solution for increasing access to tobacco cessation services and tobacco cessation medications. Any concerns related to side effects or other rare, unlikely safety concerns pale in comparison to the fact that for every three people who continue to smoke, two of them will die of a smoking related illness.⁷ No matter what statistics are reviewed, helping people quit smoking will always be the best outcome from a public health perspective.

MPhA urges a favorable report of SB 440.

³ https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6208a8.htm?s_cid=mm6208a8_w

⁴ Miech, RA, et al.. Monitoring the Future national survey results on drug use, 1975–2017: Volume I, Secondary school students. Ann Arbor: Institute for Social Research, The University of Michigan (2018) at page 14, available at http://monitoringthefuture.org/pubs/monographs/mtf-vol1_2017.pdf (accessed Feb. 24, 2019).

National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services, Teens and E-cigarettes, available at <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/teens-e-cigarettes> (accessed Feb. 24, 2019).

⁵ DeVoe JE, et al., Receipt of Preventive Care Among Adults: Insurance Status and Usual Source of Care, *AJPH*, 2003;93(5):786-91.

⁶ Anthenelli RM, et al. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial. *Lancet* 2016. 387(10037):2507e2520.

⁷ Banks E, et al. Tobacco smoking and all-cause mortality in a large Australian cohort study: findings from a mature epidemic with current low smoking prevalence. *BMC Medicine* 2015. 13(38). <https://doi.org/10.1186/s12916-015-0281-z>

EPIC_Brian Hose_FAV_SB0440

Uploaded by: hose, brian

Position: FAV



A Network Of
Independently Owned
Pharmacies

Testimony offered on behalf of:
EPIC PHARMACIES, INC.

IN SUPPORT OF:
SB 440 – Pharmacists - Aids for the Cessation of Tobacco Product Use

Senate Education, Health and Environmental Affairs Committee
In the Senate - Hearing 2/13 at 1:00 p.m.

EPIC Pharmacies **SUPPORTS SB 440** – Pharmacists - Aids for the Cessation of Tobacco Product Use.

EPIC Pharmacies are positioned in hundreds of communities across the state and represent the front line of healthcare providers caring for Maryland communities and your constituents. As the most accessible members of the healthcare team, pharmacists are uniquely positioned to influence public health efforts in the area of smoking cessation.

Cigarette smoking remains the leading cause of preventable death and disability in the United States with over 16 million Americans limited by a smoking-related disease, amounting to \$170 billion annually in medical costs. Pharmacists are the medication experts who are ready, willing, and trained to identify the most appropriate medications or nicotine replacement therapy for these patients. Currently, there are 12 states that allow pharmacists to prescribe tobacco cessation aids with some having such authority since 2004. Other states are achieving higher quit rates thanks to the expanded toolbox that they have given to their pharmacists. Please help us bring this success to Maryland by expanding the authority of Pharmacists through passage of SB0440.

EPIC Pharmacies respectfully requests a **FAVORABLE REPORT on SB 440.**

Sincerely,

A handwritten signature in black ink, appearing to read "Brian M. Hose".

Brian M. Hose, PharmD
EPIC PharmPAC Chairman
Owner / CEO
Sharpsburg Pharmacy
301-432-7223
brian.hose@gmail.com

MDChainDrugStoreAssoc_FAV_SB440

Uploaded by: LOCKLAIR, CAILEY

Position: FAV



February 7, 2020

Chairman Paul G. Pinsky
Maryland Senate Education, Health, and Environmental Affairs Committee
2 West
Miller Senate Office Building
Annapolis, Maryland 21401

RE: Support for SB440- Expanding Access to Tobacco Cessation Services at Pharmacy Healthcare Destinations

Dear Chairman Pinsky:

On behalf of the 931 chain pharmacies operating in Maryland, the National Association of Chain Drug Stores (NACDS) and the Maryland Association of Chain Drug Stores (MACDS) offer our strong support for SB440 that would expand Marylanders’ access to tobacco cessation aids at pharmacy healthcare destinations as well as appropriate corresponding coverage for the provision of this pharmacy care service. We applaud you, Chairman Pinsky, and your fellow members of the Maryland Senate Education, Health, and Environmental Affairs Committee for your tremendous efforts to identify opportunities that expand access to care throughout the state. Synergistic to these efforts, we urge you and the Committee to advance this bill.

Despite extensive public health and policy efforts to curb smoking over several decades, currently about 34 million adults in the U.S. smoke cigarettes and healthcare costs attributed to smoking have risen to more than \$170 billion per year.ⁱ While Maryland’s smoking rates for adults (nearly 14%) and high schoolers (about 8%) are lower than the national average, smoking-related healthcare costs Maryland more than \$2.7 billion per year and related losses in productivity cost more than \$2.2 billion.ⁱⁱ The Centers for Disease Control and Prevention (CDC) estimates that about 50% of daily adult smokers in Maryland quit smoking for one or more days in 2017,ⁱⁱⁱ indicating a desire to change behavior. Notably, Maryland has made several investments toward curbing tobacco use such as a strong investment in its quit line and having a private insurance mandate provision for cessation.^{iv} However, given the continued high public health and financial burden of tobacco use in the state, additional reform and expanded access to tobacco cessation aids is still needed.

The successful implementation of SB440 would address this important public health and economic issue by leveraging community pharmacists to deliver accessible, affordable, and well-coordinated care to Marylanders at pharmacy healthcare destinations. Evidence has shown that patients visit pharmacies ten times more frequently than other healthcare providers.^v According to U.S. Surgeon General Dr. Jerome Adams in 2019,

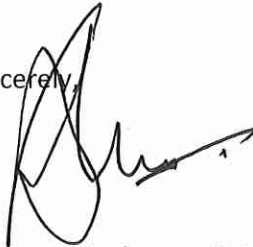
*“Clinical interventions for smoking cessation are critical if we are to achieve our goal of eliminating the devastating effects of smoking on public health. Primary care physicians, nurses, **pharmacists**, and other providers in all medical disciplines and in all healthcare environments should take advantage of those opportunities to inform and encourage smokers to quit.”^{vi}*

Currently 12 states have passed legislation or regulations that expand patient access to tobacco cessation aids.^{vii} Since 2004, New Mexico has allowed pharmacists to prescribe tobacco cessation products with great success. In a New Mexico study conducted over six years, 1,437 study participants received tobacco cessation services at pharmacies with average quit rates at 1 month (about 29%), 3 months (about 23%), and 6 months

(about 18%). This study demonstrated that pharmacist-led tobacco cessation programs maintained quit rates similar to programs run by other healthcare professionals. The authors concluded that broader pharmacist involvement, via prescribing and related programs, expand access to quality care and support avoidance of tobacco-related health outcomes.^{viii} Evidence indicates that face-to-face counseling is the “gold standard” for behavioral treatment of nicotine dependence,^{ix} and Marylanders could benefit from such care at their pharmacy healthcare destination. In a systematic review of 49 studies totaling a combined 19,000 participants, experts concluded that face-to-face tobacco cessation services – and individualized counseling – are more effective than other care options.^x And in order to sustain the delivery of high quality care, it is essential to deploy the necessary reimbursement infrastructure for the provision of patient care services. In 2019, the state of California passed legislation allowing pharmacists to receive appropriate reimbursement for the furnishing of nicotine replacement therapy products.^{xi} Additionally, the 2019 U.S. Surgeon General Report related to tobacco cessation discusses the importance of implementing appropriate reimbursement measures in order to increase the delivery of interventions, namely via allowing more clinicians to bill for tobacco cessation services and expanding pharmacists’ scope of practice to allow prescriptive authority for tobacco cessation therapies.^{xii} Marylanders would greatly benefit from having the opportunity to access quality, affordable, tobacco cessation aids from their community pharmacy healthcare destination.

NACDS and MACDS strongly urge you and the Committee to advance SB 440, as doing so would expand access to Marylander care and broadly improve patient health. Further, doing so would be an important step forward toward curbing tobacco use by children and adults in Maryland. We welcome the opportunity to work collaboratively with you and the Committee on this and other issues that expand Marylander access to high-quality care.

Sincerely,



Steven C. Anderson, IOM, CAE
President and Chief Executive Officer
National Association of Chain Drug Stores



Cailey E. Locklair
President
Maryland Association of Chain Drug Stores

ⁱ Smoking Cessation: A Report of the Surgeon General. HHS. 2020. <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>

ⁱⁱ Truth Initiative. Tobacco Use in Maryland 2019. Jun 2019. <https://truthinitiative.org/research-resources/smoking-region/tobacco-use-maryland-2019>

ⁱⁱⁱ CDC, Behavioral Risk Factor Surveillance System, State Tobacco Activities Tracking and Evaluation System, 2017.

^{iv} Truth Initiative. Tobacco Use in Maryland 2019. Jun 2019. <https://truthinitiative.org/research-resources/smoking-region/tobacco-use-maryland-2019>

^v *Studied in Medicaid patient populations* Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. <http://www.ncmedicaljournal.com/content/78/3/198.full>

^{vi} Smoking Cessation: A Report of the Surgeon General. HHS. 2020. <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>

^{vii} NASPA. Pharmacist Prescribing: Tobacco Cessation Aids. August 2019. <https://naspa.us/resource/tobacco-cessation/>

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MDHA_FAV_SB440

Uploaded by: McDonough, Caitlin

Position: FAV



The Honorable Paul Pinsky
Chair, Senate Education, Health and
Environmental Affairs Committee
Miller Senate Office Building, 2 West
11 Bladen Street
Annapolis, MD 21401

The Honorable Delores Kelley
Chair, Senate Finance Committee
Miller Senate Office Building, 3 East
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Annapolis, MD 21401

February 13, 2020

**TESTIMONY IN SUPPORT OF SENATE BILL 440 – PHARMACISTS – AIDS FOR THE
CESSATION OF TOBACCO PRODUCT USE**

Dear Chairs Pinsky and Kelley:

The Maryland Dental Hygienists Association (MDHA) is an organization seeking to improve the public's total health by advancing the art and science of dental hygiene, including ensuring access to quality oral health care, increasing awareness of the cost-effective benefits of preventative dental services, promoting the highest standards of dental hygiene education, licensure, practice and research, and representing and promoting the interests of dental hygienists in Maryland. In keeping with that mission, MDHA takes this opportunity to voice its support for Senate Bill 440, which expands the scope of practice for licensed pharmacists, who meet specified requirements, to include prescribing and dispensing tobacco cessation aids and mandates Medicaid coverage for those services.

Tobacco use is one of the leading causes of preventable illness in the United States. In addition to systemic health concerns, tobacco use has significant oral health consequences. According to the American Dental Association, cigarette smoking can lead to a variety of oral effects, including gingival recession, impaired healing following periodontal therapy, oral cancer, mucosal lesions, periodontal disease and tooth staining. Due to the serious oral health implications, MDHA strongly supports efforts to promote the recognition, prevention and cessation of tobacco use. Expanding and incentivizing cessation efforts is essential to preventing subsequent oral health effects and a fundamental basis for the preventative dental services our members provide.

The 2008 U.S. Public Health Service clinical practice guidelines for treating tobacco use and dependence found that counseling and medication are effective when used by themselves for treating tobacco dependence; however, the combination of counseling plus medication was more effective than either method alone. Expanding the scope of licensed pharmacists to prescribe and dispense tobacco cessation aids will increase convenience and accessibility for these products. MDHA supports any policy that makes these important and effective aids more readily available to patients. Additionally, MDHA supports efforts to ensure full coverage for these products for preventative use, and remove barriers to access based on affordability.

MDHA takes this opportunity to thank Senator Hayes for his leadership on this important issue, and will continue to work with him and members of the Senate Education, Health and Environmental Affairs and Finance Committees to develop and implement effective dental health policy for patients in Maryland. MDHA urges the Committees' favorable consideration of Senate Bill 440.

Hayes_FWA_SB440

Uploaded by: Senator Hayes, Senator Hayes

Position: FAV

ANTONIO HAYES
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THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

February 13, 2020

**Testimony in Support of SB 440:
Pharmacists - Aid for the Cessation of Tobacco Product Use**

Dear Chair Pinsky and Members of the Senate Education, Health and Environmental Affairs Committee:

Smoking is one of the leading causes of premature and preventable death in the USA. **SB 440** would authorize licensed pharmacists to prescribe and dispense medications approved by the U.S. Food and Drug Administration (FDA) as tobacco cessation aids. Currently, Maryland law covers tobacco cessation medication and services offered by licensed health care practitioners with Medicaid and the Maryland Children's Health Program (MCHP). **SB 440** would simply extend those same provisions to licensed pharmacists in Maryland.

Though there are over-the-counter options for smoking cessation, these options are less effective and insurance companies often do not cover the costs. Expanding the scope of practice of licensed pharmacists to include tobacco cessation counseling and prescribing of tobacco cessation aids is anticipated to increase utilization of such services by Medicaid and MCHP enrollees. This will increase the chances of getting Marylanders to quit smoking and improve their health habits. Reduced smoking rates will aid in the prevention and reduced impacts of chronic diseases such as high blood pressure, diabetes, heart disease, lung disease, and many types of cancers.

Authorizing pharmacists to provide tobacco cessation aids is safe, and the Center for Disease Control (CDC) has stated that use of cessation medications is appropriate for most adult smokers. In fact, there are 12 states that have passed legislation so far that have statutes or regulations addressing pharmacist prescribing of tobacco cessation aids (without a collaborative practice agreement or local standing order): Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Maine, Missouri, New Mexico, Oregon, and West Virginia. Of those, Arkansas and Missouri allow pharmacists to prescribe nicotine replacement therapy. Other states are also in the process of considering similar legislation.

Tobacco cessation aids are proven to increase quit rates among smokers but are underutilized. **SB 440** would help ensure that tobacco cessation is more accessible and convenient to Marylanders by authorizing trained pharmacists to prescribe these aids.

I urge this body to vote favorably on SB 440.

Respectfully,



Senator Antonio L. Hayes
Chair, Baltimore City Senate Delegation
40th Legislative District - MD

NASPA_Shipman_FAV_SB 440

Uploaded by: Shipman, Allie Jo

Position: FAV



National Alliance of State Pharmacy Associations

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February 13, 2020

Written Testimony Submitted for the Record to the Maryland Senate Education, Health, and Environmental Affairs Committee

SB 440 Pharmacists – Aids for the Cessation of Tobacco Product Use

SUPPORT

The National Alliance of State Pharmacy Associations (NASPA) joins the Maryland Pharmacists Association in supporting SB 440 which will improve access to important tobacco cessation medications.

NASPA works with state pharmacy associations and other partners across the country on state policy affecting the profession of pharmacy. Much of NASPA's policy work focuses on pharmacist-provided patient care services, including pharmacist prescribing. We have tracked this topic across the states for a number of years and coordinated the development of consensus-based policy recommendations.

State Landscape

Currently, twelve states have passed legislation allowing patients to access tobacco cessation aids directly from pharmacists. New Mexico's legislation passed in 2001 and the subsequent regulations, jointly approved by the New Mexico Boards of Pharmacy and Medicine, went into effect in 2004.¹ In the fifteen plus years since pharmacists were first able to prescribe tobacco cessation medications, there have been no reported problems.

Following New Mexico's lead are Arkansas, Arizona,² California,³ Colorado,⁴ Idaho,⁵ Indiana,⁶ Iowa,⁷ Maine,⁸ New Mexico, Oregon. West Virginia⁹

The Need for Increased Access

While the adult smoking rate has been in decline for a number of years in the United States (down to 14% in 2017), certain subgroups of Americans still use tobacco at much higher rates.¹⁰ Smoking rates are increased for people with less education (42%), people with no insurance (31%), and people who are covered by Medicaid (28%), among others.¹¹ Not only do people who smoke have higher healthcare costs, an estimated 480,000 people die each year from smoking-related illness—that's the equivalent of about twenty-two 747 airplanes crashing every week.¹² With e-cigarette use on the rise, and data to show teen e-cig users are much more likely to start smoking cigarettes, tobacco use is a problem unlikely to go away soon.¹³

Pharmacists Are Accessible and Can Help People Quit

Not only are pharmacists highly accessible¹⁴ and highly trained,¹⁵ research shows that pharmacists can effectively help people quit smoking by providing cessation counseling and prescribing tobacco cessation medications.¹⁶

Research has demonstrated that pharmacist-provided tobacco cessation services are just as effective as those services provided by other healthcare providers. In one New Mexico based study of 1,437 smokers who received pharmacist-provided tobacco cessation services, quit rates were similar to

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those achieved by other healthcare professionals. Of note, study participants were recruited by the participating pharmacists at local community pharmacies and 64% of the patients in the study did not have health insurance. This finding shows that pharmacists can serve as an access point for patients who otherwise would not receive preventive health services.¹⁷

Support for Pharmacist-Provided Tobacco Cessation Services

Recognizing the value of pharmacists' accessibility in the community, medication expertise, and evidence supporting pharmacist-provided tobacco cessation services, many organizations have supported the concept – including these:

- Centers for Disease Control and Prevention¹⁸
- Centers for Medicare & Medicaid Services¹⁹
- Tobacco Control Network (Association of State and Territorial Health Officials²⁰)

Pharmacists are Qualified to Prescribe Tobacco Cessation Aids

Pharmacists, who earn a Doctor of Pharmacy degree before sitting for the national licensing exam, receive six to eight years of clinical training that includes tobacco cessation training.²¹ Pharmacist education focuses on pharmacotherapy and the provision of patient-centered care.²² Even if it were true that pharmacists need further training, policymakers need not reject the concept of pharmacist prescribing tobacco cessation medications altogether. Some states have accommodated those opposed to increased access to tobacco cessation based on pharmacists' qualifications by including required education as a prerequisite to pharmacist prescriptive authority. The language in SB 440 (page 4, line 21) is consistent with other states' approaches to pharmacist training.

Tobacco Cessation Aids are Safe and Effective

Often in states considering language like SB 440, opponents attack the safety of tobacco cessation products themselves, namely that of varenicline (Chantix) and bupropion (Zyban).²³ But the evidence, and even the Food and Drug Administration (FDA), disagree. While both varenicline and bupropion label previously contained a Boxed Warning for serious mental health side effects, these warnings were removed by FDA in 2016.²⁴ The FDA based its decision to remove the warnings on the results of a large clinical trial studying the safety and efficacy of the medications, the EAGLES study.²⁵

The EAGLES study included over 8,000 participants and was double-blind, randomized, and placebo-controlled—the gold standard in medical research. This research showed that side effects from varenicline and bupropion were similar to that of the over-the-counter nicotine patch, both for patients with and without a history of psychiatric conditions. The study also demonstrated that varenicline and bupropion are more effective at helping people quit smoking than are nicotine replacement therapies, with varenicline having the highest overall quit rate. This conclusion is consistent with other research.²⁶ Clinical guidelines from the American College of Cardiology recommend varenicline as first-line therapy.²⁷ There have even been calls for varenicline to be available over-the-counter²⁸ and research funded by the National Institutes of Health is underway to examine the safety and efficacy of over-the-counter varenicline.²⁹

Conclusion

Pharmacists are a great solution for increasing access to tobacco cessation services and tobacco cessation medications. Any concerns related to side effects or other rare, unlikely safety concerns pale in comparison to the fact that for every two people who continue to smoke, one of them will die of a smoking related illness. No matter what statistics are reviewed, helping people quit smoking will always be the best outcome from a public health perspective.



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References

¹ 2001 N.M. SB 353; N.M. Code R. § 16.19.26.11.

² Ariz. Rev. Stat. § 32-1979.03.

³ Cal. Bus. & Prof. Code § 4052.9.

⁴ 3 Colo. Code Regs. § 719-1, Rule 17.00.50; State of Colorado Department of Regulatory Agencies, Colorado State Board of Pharmacy Approved Statewide Protocol for Dispensing Tobacco Cessation Products, available at <https://drive.google.com/file/d/0B-K5DhxXxJZbZTcwZ1FTZ1c2Mzg/view> (accessed Feb. 24, 2019).

⁵ Idaho Code § 54-1733E.

⁶ Ind. Code Ann. § 16-19-4-11. Indiana statute provides “the state health commissioner or the commissioner’s designated public health authority who is a licensed prescriber” with discretionary authority to issue a statewide standing order. At the time this article was published, the discretionary authority had not yet been exercised.

⁷ Iowa Code § 155A.46.

⁸ 32 M.R.S. § 13702-A(28).

⁹ Or. Rev. Stat. Ann. § 689.645; see Oregon Board of Pharmacy, Board Meeting Agenda Feb. 6-7, 2019, page 79-80, available at <https://www.oregon.gov/pharmacy/Imports/Agendas/AgendaFeb2019.pdf> (accessed Feb. 24, 2019). Discretionary authority provided in statute, currently under review in the regulatory process.

¹⁰ See <https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html>.

¹¹ See *id.*

¹² See U.S. Department of Health and Human Services, The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General, Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014; Centers for Disease Control and Prevention, QuickStats: Number of Deaths from 10 Leading Causes—National Vital Statistics System, United States, 2010. Morbidity and Mortality Weekly Report 2013;62(08);155, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6208a8.htm?s_cid=mm6208a8_w, (accessed Feb. 24, 2019).

¹³ See Miech, RA, et al., Monitoring the Future national survey results on drug use, 1975–2017: Volume I, Secondary school students. Ann Arbor: Institute for Social Research, The University of Michigan (2018) at page 14, available at http://monitoringthefuture.org/pubs/monographs/mtf-vol1_2017.pdf (accessed Feb. 24, 2019); National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services, Teens and E-cigarettes, available at <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/teens-e-cigarettes> (accessed Feb. 24, 2019).

¹⁴ See National Association of Chain Drug Stores, Face-to-face with community pharmacies, available at <http://www.nacds.org/pdfs/about/rximpact-leavebehind.pdf> (accessed Feb. 24, 2019). Ninety-one percent of Americans live within five miles of a community pharmacy.

¹⁵ See Pharmacists for Healthier Lives, <https://pharmacistsforhealthierlives.org>, (accessed Feb. 24, 2019). Pharmacists receive at least six years of higher education and are required to earn a Doctor of Pharmacy degree before sitting for the licensure exam.

¹⁶ See Chen T, et al., Comparison of an Intensive Pharmacist-Managed Telephone Clinic with Standard of Care for Tobacco Cessation in a Veteran Population, *Health Promot Pract*, 2013; 15(4):512-520; see also Shen X, et al., Quitting Patterns and Predictors of Success Among Participants in a Tobacco Cessation Program Provided by Pharmacists in New Mexico, *J Manag Care Pharm*, 2014;20(6):579-87.

¹⁷ See DeVoe JE, et al., Receipt of Preventive Care Among Adults: Insurance Status and Usual Source of Care, *AJPH*, 2003;93(5):786-91.

¹⁸ See Centers for Disease Control and Prevention, Pharmacists: Help Your Patients Quit Smoking, available at <https://www.cdc.gov/tobacco/campaign/tips/partners/health/pharmacist/index.html> (accessed Feb. 24, 2019); Department of Health and Human Services, Centers for Medicare & Medicaid Services.



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¹⁹ See CMCS Informational Bulletin, State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols, Jan. 17, 2017, available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf> (accessed Feb. 24, 2019).

²⁰ Tobacco Control Network, Access to Tobacco Cessation Medication Through Pharmacists, Feb 8, 2017, available at <http://www.astho.org/Prevention/Tobacco/Tobacco-Cessation-Via-Pharmacists/> (accessed Feb. 24, 2019).

²¹ See Corelli RL, et al., Evaluation of a train-the-trainer program for tobacco cessation, *Am J Pharm Educ.* 2007;71(5):109.

²² See Accreditation Council for Pharmacy Education, Accreditation standards and key elements for the professional program in pharmacy leading to the Doctor of Pharmacy degree, 2015, available at <https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf> (accessed Feb. 24, 2019).

²³ *Supra* note 49.

See Idaho Senate, Health and Welfare Committee Minutes, Feb. 1, 2017, available at https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2017/standingcommittees/170201_sh&w_0300AM-Minutes.pdf (accessed Feb. 24, 2019).

²⁴ See U.S. Food and Drug Administration, Drug Safety Communication: FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings, December 16, 2016, available at <https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm> (accessed Feb. 24, 2019).

²⁵ See Anthenelli RM, et al., Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial, *Lancet*, 2016;387(10037):2507e2520.

²⁶ Cahill K, et. al., Pharmacological interventions for smoking cessation: an overview and network meta-analysis, *Cochrane Database Syst Rev.* 2013;(5).

²⁷ See Barua RS, et. al., 2018 ACC expert consensus decision pathway on tobacco cessation treatment. *J Am Coll Cardiol* 2018;72:3332–65.

²⁸ See Leischow SJ, Increasing Smoking Cessation in the United States: Expanding the Availability of Over-the-Counter Medications, *JAMA* 2019;321(6): 541-42.

²⁹ See U.S. National Library of Medicine, Varenicline OTC Trial on Efficacy and Safety (VOTC), *ClinicalTrials.gov* Identifier: NCT03557294, available at: <https://clinicaltrials.gov/ct2/show/NCT03557294> (accessed Feb. 24, 2019).

Board of Pharmacy_FAV__SB440

Uploaded by: Speights-Napata, Deena

Position: FAV



Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue, Baltimore, Maryland 21215-2299

Kevin M. Morgan, Board President | Deena Speights-Napata, Executive Director

February 13, 2020

The Honorable Senator Paul G. Pinsky
Chair, Senate Education, Health, and Environmental Affairs Committee
2 West, Miller Office Building
Annapolis, MD 21401-1991

RE: Senate Bill 440 – Pharmacists – Aids for the Cessation of Tobacco Product Use – Letter of Support

Dear Chair Pinsky:

The Maryland Board of Pharmacy (the “Board”) is submitting this letter of Support for Senate Bill 440 – Pharmacists – Aids for the Cessation of Tobacco Product Use.

Senate Bill 440 expands a pharmacist’s scope of practice to include the prescribing and dispensing of tobacco cessation aids. This will expand public access to these important treatments. By expanding access to tobacco cessation products, this legislation will promote public health in Maryland and advance the Board of Pharmacy’s mission to promote quality healthcare in the field of pharmacy. For these reasons, the Board of Pharmacy extends its formal support for this legislation.

I hope this information is useful. If you would like to discuss this further, please contact me at 410-764-4753 or deena.speights-napata@maryland.gov.

Sincerely,

Deena Speights-Napata, M.A.
Executive Director
Maryland Board of Pharmacy

MDRHA_FAV_SB440

Uploaded by: Wilson, Lara

Position: FAV



Statement of Maryland Rural Health Association

To the Education, Health, and Environmental Affairs Committee

February 13, 2020

Senate Bill 440: Pharmacists – Aids for the Cessation of Tobacco Product Use

POSITION: SUPPORT

Senators Hayes, Benson, Ellis, Kramer, Patterson, and Washington, Chair Pinsky, Vice Chair Kagan, and members of the Education, Health, and Environmental Affairs Committee, the Maryland Rural Health Association (MRHA) is in SUPPORT of Senate Bill 440: Pharmacists – Aids for the Cessation of Tobacco Product Use.

This legislation would authorize a pharmacist who meets the requirements of certain regulations to prescribe and dispense aids for the cessation of the use of tobacco products; requiring the State Board of Pharmacy, by September 1, 2021, to adopt certain regulations; requiring the Maryland Medical Assistance Program and the Maryland Children's Health Program to provide coverage for certain services rendered by a licensed pharmacist under the Act to the same extent as certain services rendered by any other licensed health care practitioner; etc.

MRHA's mission is to educate and advocate for the optimal health and wellness of rural communities and their residents. Membership is comprised of health departments, hospitals, community health centers, health professionals, and community members in rural Maryland.

Rural Maryland represents almost 80 percent of Maryland's land area and 25% of its population. Of Maryland's 24 counties, 18 are considered rural by the state, and with a population of over 1.6 million they differ greatly from the urban areas in the state.

Maryland law states that "many rural communities in the State face a host of difficult challenges relating to persistent unemployment, poverty, changing technological and economic conditions, an aging population and an out-migration of youth, inadequate access to quality housing, health care and other services, and deteriorating or inadequate transportation, communications, sanitations, and economic development infrastructure." (West's Annotated Code of Maryland, State Finance and Procurement § 2-207.8b)

The 2018 Maryland Rural Health Plan (www.MDRuralHealthPlan.org), an extensive assessment of Maryland's rural health needs, illustrates the increase prevalence of adult and youth smoking across our 18 rural jurisdictions. MRHA believes this legislation is important to support our rural communities and we thank you for your consideration.

Lara Wilson, Executive Director, larawilson@mdruralhealth.org, 410-693-6988

ACNM_Robyn Elliott_FAV_SB 0440

Uploaded by: Elliott, Robyn

Position: UNF



Committee: Senate Education, Health, and Environmental Affairs

Bill Number: SB 440

Bill Title: Pharmacists - Aids for the Cessation of Tobacco Product Use

Date: February 13, 2020

Position: Oppose

The Maryland Affiliate of the American College of Nurse-Midwives (ACNM) opposes *Senate Bill 440– Pharmacists – Aids for the Cessation of Tobacco Product Use – Prescribing and Dispensing*. The bill would authorize pharmacists to prescribe and dispense medications to assist patients in reducing or eliminating tobacco use.

ACNM supports the expansion of access to tobacco cessation products among Marylanders. We view pharmacists as valuable partners in counseling consumers about over-the-counter smoking cessation tools. However, we have deep concerns about the involvement of pharmacists in prescribing because:

- Pharmacists do not have the education to allow them to access or diagnosis the serious psychiatric disorders that can be side effects to the use of Chantix and Wellbutrin. Pharmacists also do not typically practice in settings that afford the level of privacy needed to discuss mental health symptoms; and
- Pharmacists do not have authority to either order or interpret lab tests, or manage lab abnormalities, that would be needed to monitor the kidney and liver functions of patients and make decisions about dosing, as is commonly needed for patients taking these medications.

Because of these concerns, we ask for an unfavorable report. If we can provide any additional information, please contact Robyn Elliott at (443) 926-4443 or relliott@policypartners.net.

MNA_Robyn Elliott_UNF_SB 0440_

Uploaded by: Elliott, Robyn

Position: UNF



Committee: Senate Education, Health, and Environmental Affairs Committee

Bill Number: SB 440

Bill Title: Pharmacists – Aids for the Cessation of Tobacco Product Use – Prescribing and Dispensing

Date: February 13, 2020

Position: Oppose

The Maryland Nurses Association (MNA) opposes *Senate Bill 440 – Pharmacists – Aids for Cessation of Tobacco Product Use – Prescribing and Dispensing*. The bill authorizes pharmacists to prescribe and dispense medications approved by the Food and Drug Administration for tobacco cessation. MNA views pharmacists as strong partners in the health care team. We have supported expansion of their scope in terms of prescribing contraceptives and administering vaccines. Unfortunately, we have too many patient safety concerns to support expanding pharmacists’ scope to prescribing certain tobacco cessation medications.

To utilize tobacco cessation medications and products effectively and safely, health care practitioners need to order and interpret medical tests as well as continuously monitor their patients for signs of side effects. MNA believes that these functions are far outside of the scope of pharmacists. Even with additional training, pharmacists will not be able to assess or diagnosis the serious side effects that may affect patients, order the medical laboratory tests needed for monitoring, or interpret the laboratory tests to adjust dosages or make decisions about the discontinuation of the medication.

Psychiatric Side Effects

Prescribers of the primary tobacco cessation medications, Chantix and Zyban, must have the clinical education and experience to monitor patients for psychiatric side effects.

- In the labeling for Chantixⁱ, Pfizer advises prescribers that there have been “postmarketing reports of serious or clinically significant neuropsychiatric adverse events have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide.” The labeling advises prescribers to “observe patients attempting to quit smoking with CHANTIX for the occurrence of such symptoms and instruct them to discontinue CHANTIX and contact a healthcare provider if they experience such adverse events”

- In the labeling for Wellbutrin (under the name Zyban)ⁱⁱ, GlaxoSmithKline gives prescribers similar advice, “All patients being treated with bupropion for smoking cessation treatment should be observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. These symptoms, as well as worsening of pre-existing psychiatric illness and completed suicide have been reported in some patients attempting to quit smoking while taking ZYBAN in the postmarketing experience. When symptoms were reported, most were during treatment with ZYBAN, but some were following discontinuation of treatment with ZYBAN. These events have occurred in patients with and without pre-existing psychiatric disease; some have experienced worsening of their psychiatric illnesses.”

Kidney and Liver Functions

Prescribers monitor the liver and kidney functions of individuals who take tobacco cessation products. Ordering and interpreting tests for liver and kidney functions is not within the scope of pharmacists. As an example of consumer information about Zyban, the Mayo Clinic advised patient as follows, “However, elderly patients may be more sensitive to the effects of this medicine and are more likely to have age-related kidney or liver problems, which may require caution and an adjustment in the dose for patients receiving bupropion.”ⁱⁱⁱ This is echoed in the labeling which indicates that the “patient should be closely monitored for possible adverse effects that could indicate high drug or metabolite levels.”^{iv}

Medication vs. the Patch

Prescribers should be able to utilize medical tests to make determinations dosages and which products would be most effective. In a study by the Vanderbilt University Medical Center, researchers recommended that efficiency of tobacco cessation products would be improved by a use of a blood test on how quickly a patient metabolizes nicotine. Depending on the results, a health care practitioner would recommend either Chantix or a nicotine patch.^v

Conclusion

Thank you for your consideration of our testimony. In light of the serious implications for patient safety, we urge an unfavorable vote. If we can provide any further information, please contact Robyn Elliott at relliott@policypartners.net or (443) 926-3443.

ⁱ HIGHLIGHTS OF PRESCRIBING INFORMATION, CHANTIX® (varenicline) tablets, for oral use , Initial U.S. Approval: 2006, Pffizer. Revised 6/2018.

ⁱⁱ PRESCRIBING INFORMATION - WELLBUTRIN (bupropion hydrochloride) Tablets , GlaxoSmithKline.

ⁱⁱⁱ <https://www.mayoclinic.org/drugs-supplements/bupropion-oral-route/before-using/drg-20062478>

^{iv} Ibid

^v Nicotine Metabolism-informed Care for Smoking Cessation: A Pilot Precision RCT. [Quinn S Wells, MD, PharmD, MSCI](#) et al. *Nicotine & Tobacco Research*, Volume 20, Issue 12, 15 November 2018, Pages 1489–1496.

MD Dept of Health_Info_SB0440

Uploaded by: Boyer, Andy

Position: INFO



DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

February 13, 2020

The Honorable Paul G. Pinsky
Chair, Education, Health and Environmental Affairs Committee
2 West, Miller Senate Office Building
Annapolis, MD 21401

RE: SB 440 Pharmacists - Aids for the Cessation of Tobacco Product Use - Letter of Information

Dear Chair Pinsky and Committee Members:

The Maryland Department of Health (the Department) is submitting this letter of information for Senate Bill 440 (SB 440) titled, "Pharmacists - Aids for the Cessation of Tobacco Product Use." SB 440 would expand the role of pharmacists to include tobacco cessation counseling and prescription of related tobacco cessation products, and require Medicaid and the Maryland Children's Health Program to provide coverage for services rendered by licensed pharmacists.

The Public Health Service has concluded that effective cessation treatments include individual, group, and/or phone counseling, as well as seven FDA-approved cessation aids.¹ Pharmacists are well positioned to provide tobacco cessation aids, as they are often more available than physicians without an appointment and accessible within the communities they serve.² Eight states currently have programs in place allowing pharmacists to prescribe cessation aids. An additional four states have pending regulations.^{3,4,5}

This bill will have a fiscal impact on the Department. Medicaid enrollees use tobacco at significantly higher rates than the general population (30 percent vs. 18 percent), and the Affordable Care Act requires Medicaid programs to cover all FDA-approved tobacco cessation aids with a written prescription.^{6,7} As pharmacists are already authorized provider types under Medicaid, the Department estimates that expanding coverage for tobacco cessation counseling and prescription of tobacco cessation products to pharmacists would result in a 10% increase in delivery of counseling services and related prescribing annually.

If you have additional questions, please contact Mr. Webster Ye, Director of Governmental Affairs, at (410) 260-3190 or webster.ye@maryland.gov.

Sincerely,

Robert R. Neall
Secretary

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- ¹ Fiore MC, Jaen CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline, May 2008, U.S. Department of Health and Human Services; retrieved 31 January 2020 at <https://www.ncbi.nlm.nih.gov/books/NBK63952/>.
- ² Dent, L, Harris KJ, and Noonan CW, *Randomized Trial Assessing the Effectiveness of a Pharmacist Delivered Program for Smoking Cessation*. The annals of Pharmacotherapy. 2009;43(2):194-201; retrieved 4 February 2020 at <https://journals.sagepub.com/doi/10.1345/aph.1L556>.
- ³ Tobacco Control Network: *Access to Tobacco Cessation Medication through Pharmacists*; retrieved 2 February 2020 at <https://www.astho.org/Prevention/Tobacco/Tobacco-Cessation-Via-Pharmacists/>.
- ⁴ Adams, A., Hudmon, K., Journal of the American Pharmacists Association, "Pharmacist prescriptive authority for smoking cessation medications in the United States, Volume 58, Issue 3, 253 – 257; retrieved 2 February 2020 at [https://www.japha.org/article/S1544-3191\(18\)30001-3/fulltext](https://www.japha.org/article/S1544-3191(18)30001-3/fulltext).
- ⁵ Pharmacist Prescribing: Tobacco Cessation Aids; retrieved 4 February 2020 at <https://naspa.us/resource/tobacco-cessation/>.
- ⁶ Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey, 2012. Analysis by the American Lung Association, Research and Program Services Division; retrieved 31 January 2020 at <https://www.lung.org/assets/documents/tobacco/barriers-to-accessing-tobacco.pdf>.
- ⁷ Centers for Disease Control and Prevention. State Tobacco Activities Tracking and Evaluation: What Are Medicaid Programs Required to Cover for Tobacco Cessation; retrieved 31 January 2020 at https://www.cdc.gov/statesystem/factsheets/medicaid/Cessation.html#anchor_1562854662.