



National Alliance of State Pharmacy Associations

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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).