



**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 Chantix<sup>i</sup>, 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)<sup>ii</sup>, 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.”<sup>iii</sup> 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.”<sup>iv</sup>

### **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.<sup>v</sup>

### **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](mailto:relliott@policypartners.net) or (443) 926-3443.

---

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

<sup>ii</sup> PRESCRIBING INFORMATION - WELLBUTRIN (bupropion hydrochloride) Tablets , GlaxoSmithKline.

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

<sup>iv</sup> Ibid

<sup>v</sup> 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.