



JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

March 21, 2019

The Honorable Brad Little
Governor
State of Idaho
Office of the Governor
P.O. Box 83720
Boise, ID 83720

Re: AMA Opposition to Idaho H.B. 182

Dear Governor Little:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I write to express our **strong opposition** to House Bill (H.B.) 182. This bill would allow pharmacists to independently diagnose and prescribe drugs to patients, including controlled substances. If enacted, H.B. 182 would be, by far, the most liberal expansion of pharmacist scope of practice in the nation. The AMA is deeply concerned this legislation grants pharmacists wide latitude to prescribe medications to patients, young and old, regardless of the severity or complexity of the patient's condition and including such illnesses as cancer, bipolar disorder, glaucoma, hypertension and diabetes. The AMA is deeply concerned with how this legislation is drafted and the assumption that it will be applied conservatively. Make no mistake, this legislation allows pharmacists to provide medical care for which they are not trained, without access to patients' full medical records, in a setting that is not conducive to performing a full medical examination or protecting patients' privacy. This bill is illogical and impractical in its application and raises serious patient safety concerns. The examples are numerous and frightening; we provide just a few below to show how this legislation threatens the health and safety of patients in Idaho and, in practice, could result in disastrous consequences for patients in Idaho. It is for these reasons, **we strongly urge you to veto H.B. 182.**

Pharmacists do not have the education and training to independently diagnose and prescribe

Pharmacists are valuable members of the health care team. As experts in medication and medication management, pharmacists have a longstanding relationship of working hand in hand with physicians under collaborative practice agreements. Collaborative practice agreements allow pharmacists and physicians to each play a key role in providing patient care based on the education and training of each provider. Physicians complete more than 10,000 hours of clinical

education and training during their four years of medical school and three-to-seven years of residency training. It is through this broad-based education that physicians are trained to provide complex differential diagnoses, develop a treatment plan that addresses multiple organ systems and order and interpret tests within the context of a patient's overall health condition. By sharp contrast, pharmacists attend four years of pharmacy school, which includes 1,700 hours of practice experience. **Throughout their didactic education and practice experience, pharmacists are trained to function as the medication expert within a collaborative health care team.** Neither the didactic component of pharmacy school or practice experiences prepare pharmacists to develop the clinical judgment similar to a physician with regard to diagnosis, assessment of illness/condition, formulation of a treatment plan or the provision of independent medical care or medication therapy. Yet, H.B. 182 would allow pharmacists to independently diagnose and prescribe drugs for patients both of which are outside their education and training.

H.B. 182 allows pharmacists to prescribe drugs for any patient and any condition

Idaho currently permits pharmacists to prescribe medications for select conditions approved by the Idaho Board of Pharmacy (IBP). While far from perfect, this approach at least limits the conditions for which pharmacists can prescribe and affords interested parties the opportunity to provide comments before conditions are approved by the IBP. Throughout this regulatory process, important patient safety protections have been created, such as requiring pharmacists to inform a patient's primary care physician after writing a prescription. H.B. 182 removes the IBP from the process, thereby removing these existing patient safety sideboards, and granting pharmacists an extremely wide berth in prescriptive authority. As drafted, H.B. 182 allows pharmacists to "prescribe drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:

- (i) Do not require a new diagnosis;
- (ii) Are minor and generally self-limiting;
- (iii) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; **OR**
- (iv) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider." (emphasis added)

Because of the qualifier "or" bolded above, H.B. 182 would allow pharmacists to prescribe drugs for **any** patient who meets **any** of the four conditions above. The AMA strongly opposes pharmacists independently diagnosing and prescribing medications to patients. Pharmacists do not have the education and training to collect and assess subjective and objective clinical patient information, diagnose a patient's condition, and/or prescribe drugs for treatment. In fact,

pharmacists will not even have access to the patients' full medical record. It is our understanding the decision to prescribe medication will be primarily based on a patient completed questionnaire. This approach is fraught with serious concerns about patient safety and patient privacy.

The AMA has grave concerns about this overall approach, as well as the ability of pharmacists to prescribe for any of the four categories listed in H.B. 182. For example, 5(g)(i) allows pharmacists to prescribe medication for a patient who has a current medical diagnosis. There are no additional qualifiers for age, severity of the diagnosis or point in time in which the diagnosis is "current." That means, pharmacists could prescribe drugs for any patient diagnosed with everything from high blood pressure to bipolar disorder, glaucoma and even cancer.

Moreover, it is unclear how the pharmacist will confirm a patient has been diagnosed with a medical condition as the pharmacist does not have access to patients' medical records and is not required to consult with a patient's physician. In fact, it is our understanding this determination will be based solely on a patient completed questionnaire. Even if a pharmacist could confirm a current diagnosis, the diagnosis would have presumably been performed by a physician, who would have established a treatment plan that may or may not include prescription drugs. For patients with multiple or chronic conditions, the pharmacist may be interfering with or altering an already established, effective management plan. Any change in medication could result in less effective treatment, adverse side effects, drug to drug interactions or require further evaluation for efficacy by a physician. For example, a patient with a diagnosis of hypertension, a very common, condition could present to the pharmacy with high blood pressure, the pharmacist may prescribe a beta blocker, diuretic or other agent to control the blood pressure. However, if the patient has undisclosed asthma, a beta blocker will make the asthma worse. High blood pressure may also indicate heart failure, requiring immediate medical attention, but without the training or infrastructure in the pharmacy to perform a full medical examination this will go undetected – a potentially life-threatening situation.

Relying on a patient completed questionnaire to confirm a "current" diagnosis also raises concerns. For example, if a patient presented to the pharmacists with a current diagnosis of depression, but failed to disclose that he also suffered from multiple mental illnesses, the pharmacist may alter the patient's prescription without this information. Treatment for multiple mental illnesses is an extremely complex field within medicine, any changes in medications could result in severe aggression and potentially dangerous consequences for the patient. Also, at what point in time is a diagnosis considered "current?" Even if this were defined in the legislation, the currency of a diagnosis and need for re-evaluation by a physician varies considerably based on the age and overall health of the patient, as well as the severity and type of diagnosis. For example, if a patient presents to the pharmacy with a red eye and previous diagnosis of bacterial conjunctivitis, the pharmacists may treat the patient with a topical antibiotic, but in this instance the red eye may be a manifestation of a completely different

disease such as herpes simplex infection, anterior uveitis, narrow angle glaucoma or a myriad of other conditions. Pharmacists clearly do not have the education or training to perform differential diagnoses on the patient – at the pharmacy counter – to confirm a current diagnosis. The bill’s language allows pharmacists unfettered prescriptive authority, which is not in the best interest of Idahoans and why we oppose it.

Second, 5(g)(ii) allows pharmacists to prescribe for minor or self-limiting conditions. These terms are not defined, which is very concerning, as there are countless examples where severe life-threatening conditions can be misdiagnosed as minor and self-limiting. It is because of this risk that diagnosing medical conditions is the practice of medicine. As discussed above, neither the didactic nor practice experience component of a pharmacist education prepare pharmacists to clinically assess patients or perform differential diagnoses to discern the root cause of a symptom. As such, pharmacists are ill equipped to handle even seemingly minor conditions. Below are some real-life examples of symptoms, assessed by physicians, that may have indicated a minor condition easily treated with rest or a prescription, but with a thorough medical examination were in fact symptomatic of serious life-threatening conditions some requiring immediate medical attention.

Symptom	Possible (Minor) Diagnosis		Final (Serious) Diagnosis
Abdominal cramps and diarrhea	Stomach flu	OR	Aortic dissection
Dizziness	Vertigo	OR	Threatened stroke
Child with forearm pain and fatigue	Hurt while playing baseball	OR	Leukemia with bone marrow replacement
Low back pain	Pulled muscle from yard work	OR	Multiple myeloma cancer
Fatigue	Lack of sleep & stress at work	OR	Heart attack

As you can see, the potential for misdiagnoses is great. Idaho’s patients should not be subjected to this risky policy experiment.

H.B. 182 also allows pharmacists to prescribe drugs for patients based on a diagnosis from a Clinical Laboratory Improvement Amendments (CLIA) waived test. There are more than 1,500 CLIA waived tests, many of which require special laboratory equipment and/or specially trained personnel to perform or read. These are not pregnancy tests found on the shelves in the pharmacy. Yet H.B. 182 allows pharmacists to use these tests – all 1,500 – to “guide their diagnosis or clinical decision making” and prescribe medications to patients based on this test.

The Honorable Brad Little
March 21, 2019
Page 5

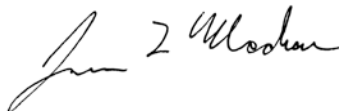
Again, this will be done without a thorough medical examination of the patient or access to the patient's full medical history. It is also unclear how these tests will be administered in a pharmacy setting. Yet, this provision allows pharmacists to diagnose and treat patients using a CLIA waived test. As discussed above, this provision is both impractical in its application and troublesome because it allows pharmacists to diagnose a medical condition, which the AMA defines as the practice of medicine, and treat this condition with prescription drugs. This unprecedented latitude afforded to pharmacists raises serious patient safety concerns.

Finally, H.B. 182 allows pharmacists to prescribe dangerous, highly addictive controlled substances. While the bill states, "[T]he board shall not adopt any rules authorizing a pharmacist to prescribe a controlled drug, compounded drug or biological product," this same provision deletes the IBP's regulatory authority to adopt rules related to the drugs for which pharmacists can prescribe. With the IBP's regulatory authority stripped and no legislative prohibition on pharmacists prescribing controlled substances, one must surmise it is permitted. This is extremely problematic, particularly in a time when the medical community is spending considerable resources to reverse the trend of rising prescription drug abuse.

For the many reasons noted above, the AMA is deeply concerned with the unprecedented expansion of scope of practice afforded to pharmacists in H.B. 182. This bill, if enacted could result in serious and irreversible disastrous consequences for Idaho's patients. **We urge you to put patients first and veto H.B. 182.**

Thank you for your consideration. If you have any questions, please contact Kim Horvath, JD, Senior Legislative Attorney, AMA Advocacy Resource Center at (312) 464-4783 or kimberly.horvath@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with the first name "James" being the most prominent.

James L. Madara, MD

cc: Idaho Medical Society