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February 7, 2023

The Honorable Ed Buttrey
Chair, House Business and Labor Committee
Montana House of Representatives
708 Central Avenue
Great Falls, MT 59401-3731

The Honorable Derek Harvey
Vice Chair, House Business and Labor Committee
Montana House of Representatives
P.O. Box 3111
Butte, MT 59701-3111

Re: **Montana Senate Bill 112 – Oppose**

Dear Chair Buttrey and Vice Chair Harvey:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am writing to **strongly oppose Montana Senate Bill 112 (SB 112)**, which would grant pharmacists the authority to diagnose, prescribe for, and treat a broad range of potentially serious health conditions. SB 112 would allow pharmacists to engage in the practice of medicine, effectively turning them into over-the-counter primary care providers with no medical training. If enacted, this bill would grant one of the broadest expansions of pharmacist scope of practice in the nation. Not only is SB 112 logistically impractical, but more importantly, it threatens the safety of Montana's patients. SB 112 allows pharmacists to provide medical care for which they are not trained, without access to patients' medical records, and in a setting that is not conducive to performing a medical examination or protecting patients' privacy. While the AMA recognizes the crucial role pharmacists play in our nation's health care system, we are deeply concerned that SB 112 crosses the line and puts Montana's patients at risk. Accordingly, we strongly urge you to oppose SB 112.

Pharmacists do not have the education and training necessary to safely diagnose and prescribe.

Pharmacists are well-trained as medication experts. It is a dangerous leap, however, to assume that pharmacy school prepares pharmacists to diagnose patients or formulate an appropriate plan of treatment, as this legislation would allow. It simply does not. Most of the Doctor of Pharmacy (PharmD) curriculum consists of instruction and labs in applied sciences and therapeutics. While pharmacy students do engage in a modest amount of "practice experiences" during their education, the training is not focused on providing medical care to patients. Notably, the practice experiences in the PharmD curriculum do not include performing a physical examination, making a diagnosis, developing differential diagnoses, or performing primary care activities. To be clear, pharmacists are not trained to examine a patient, they are not trained to make a diagnosis, and they are not trained to take on the role of primary care provider.

Moreover, pharmacists are generally not required to spend any time with patients of any particular age or with any specific medical condition over the course of their training—this means that a pharmacist could graduate without ever providing care to a child or without ever having seen a person with an illness that this legislation would authorize them to diagnose and treat. Pharmacy residencies that might give pharmacists experience in patient care are not common in the community setting. Only about 5.5 percent of pharmacists employed in community settings have undergone residency training.

Diagnosing and treating patients is the practice of medicine. In addition to medical school instruction, where medical students study the biological, chemical, pharmacological, and behavioral aspects of the human condition, physicians have more than 10,000 hours and seven-to-eleven years of postgraduate clinical education and training, through which they learn the complexities related to appropriate prescribing in multiple clinical situations and settings. Via this broad-based education, 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.

The AMA strongly opposes pharmacists independently diagnosing and prescribing medications to patients. Pharmacists lack the education, training, and experience necessary to assess subjective and objective clinical patient information, perform a comprehensive examination, diagnose a patient's condition, or prescribe pursuant to a formulated plan of treatment and as such, SB 112 must be opposed.

SB 112 is logistically impractical and a threat to patient safety.

The AMA is troubled by the breadth of this legislation. SB 112 authorizes pharmacists to prescribe medications for conditions that are "minor and generally self-limiting," for conditions that may be detected using a Clinical Laboratory Improvement Amendments (CLIA) waived test, and for any illness with which a patient has ever been diagnosed. It authorizes pharmacists to treat patients of any age and with any pre-existing health condition. If enacted, SB 112 would be one of the nation's broadest laws authorizing pharmacists to diagnose and treat–making Montana a dangerous outlier in terms of the provision of health care to its residents. It is both impractical in its application and deeply troublesome from a patient care perspective because it allows pharmacists to engage in the practice of medicine for which they are not trained, with potentially disastrous consequences.

Medical care cannot be provided over the pharmacy counter. To be clear, SB 112 would allow pharmacists—who are not trained to perform a physical examination and have no education in making a medical diagnosis—to diagnose and treat any child, adult, senior, pregnant patient, or chronically ill patient who arrives at the pharmacy, over the counter, from the pharmacy line. The pharmacist could do so without performing a physical examination, without a review of the patient's medical record, without knowledge or understanding of the patients' other medical conditions or potential co-morbidities, and regardless of whether the pharmacist has any experience treating that population. We encourage lawmakers to consider the numerous privacy and logistical concerns with the bill's proposition by simply imagining for a moment the atmosphere of one's local pharmacy chain. We also draw your attention to profound medical concerns raised by certain provisions of the bill.

Minor and generally self-limiting conditions

SB 112 allows pharmacists to prescribe for "minor and generally 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. Without a physical exam by a trained professional done in the full context of the patient's health, the severity of an illness is easily under-appreciated. Underlying causes of symptoms may go overlooked. Consider respiratory illness as an example. A cold may be "minor and generally self-limiting," but one must ask how a pharmacist might know whether the lungs are clear without any training and without actually listening to a patient's lungs? 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. Physicians are trained in residency to identify seriously ill patients and to perform differential diagnoses; pharmacists simply are not.

CLIA-waived tests

SB 112 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 SB 112 allows pharmacists to use these tests—all 1,500—to guide their diagnosis or clinical decision making and prescribe medications to patients based on the result. It is unclear how CLIA-waived tests would be administered in a pharmacy setting.

Importantly, the results of a test alone are not enough to make a conclusive diagnosis or to rule out other complications. Consider a urinary tract infection (UTI), as one example. A UTI may be contemplated as a "minor condition," diagnosable with a CLIA-waived test; however, it cannot be safely managed over the pharmacy counter. A CLIA-waived test alone is not enough to diagnose and treat a UTI. In addition to a urinalysis, cultures are often necessary to confirm infection, guide treatment, and to identify serious complications including severity of the infection, kidney stones, and even cancer. Life-threatening kidney infections can mask as a UTI and are undetectable without palpating the abdomen, which can only be done through a competent physical exam. The very presence of a UTI in a man or a child warrants further inquiry, and women with bladder cancer may be misdiagnosed with UTIs. Changes over time or recurrent UTIs call for further workup; however, the clinician must have a clear longitudinal understanding of the patient's history to recognize this. In the pharmacy setting, the pharmacist will only have access to an isolated test result and will not have the findings of a competent physical exam or the patient's medical history. In short, this example makes it clear that it is not appropriate to rely only on a CLIA-waived test to make a diagnosis or determine the appropriate course of treatment and doing so puts patients at risk.

Conditions that do not require a new diagnosis

SB 112 would allow pharmacists to prescribe medications for conditions that "do not require a new diagnosis." The AMA has grave concerns about this approach. The bill includes no qualifiers for age of diagnosis or severity of diagnosis. This means that pharmacists could lawfully prescribe drugs for any patient who has ever been diagnosed with essentially anything—from high blood pressure to bipolar disorder, to glaucoma, and even to 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. Relying on patient reporting to confirm a diagnosis raises concerns. For example, if a patient presented to the pharmacist 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 dangerous consequences for the patient.

Also, 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. In this instance, however, 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.

Even if a pharmacist could confirm a diagnosis, the diagnosis would have presumably been originally made 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, and the pharmacist may prescribe a beta blocker, diuretic, or other agent to control the blood pressure. If the patient has undisclosed asthma, however, a beta blocker will make the asthma worse. High blood pressure may also indicate heart failure, requiring immediate medical attention. It is critical to understand that without the training or infrastructure in the pharmacy to perform a full medical examination this will go undetected—a potentially life-threatening situation.

Pharmacists do not have the education or training to practice medicine nor are they interchangeable with physicians. Authorizing them to perform differential diagnoses at the pharmacy counter puts patients at risk for negative health outcomes and as such, SB 112 must be strongly opposed.

Pharmacists are already overburdened, especially in the community setting.

Finally, data suggest that pharmacists in community settings are already at capacity, without the added burden of treating illness and providing primary health care. A reputable workforce study of more than 3,000 pharmacists found that a full 75 percent of pharmacists in chain settings said they already have so much work to do that everything cannot be done well.[1] The problem appears systemic: 71 percent of all pharmacists and 91 percent of pharmacists working in pharmacy chains rated their workload as high or excessively high.[2] Scope expansions like the one proposed in SB 112 only add burden to an overburdened pharmacist workforce and threaten patient safety and must be soundly defeated.

SB 112 puts patients at risk.

As noted above and in closing, SB 112 raises serious concerns. For the many reasons noted above, the AMA is deeply concerned with the overly broad, dangerous expansion of scope of practice afforded to pharmacists in SB 112. We strongly urge you and members of the House Business and Labor Committee to oppose SB 112 because, simply put, Montanans deserve better.

If you have any questions, please contact Kimberly Horvath, JD, Senior Attorney, AMA Advocacy Resource Center, at kimberly.horvath@ama-assn.org.

Thank you for your consideration.

Sincerely,

James L. Madara, MD

cc: Montana Medical Association

[1] American Association of Colleges of Pharmacy (AACP), 2019 National Pharmacist Workforce Study Final Report, pg. 64, Jan.10, 2020. Available at: https://www.aacp.org/sites/default/files/2020-03/2019_NPWS_Final_Report.pdf

[2] *Id*. at 38