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February 7, 2023

The Honorable Lee Yancey
Chair
House Drug Policy Committee
Mississippi House of Representatives
P.O. Box 4215
Brandon, MS 39047

Re: **Mississippi House Bill 1317 – Oppose**

Dear Chair Yancey:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am writing to **strongly oppose Mississippi House Bill 1317 (HB 1317)**, which would grant pharmacists the authority to independently diagnose and prescribe medications for a wide range of potentially serious health conditions. HB 1317 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 HB 1317 logistically impractical, but more importantly, it threatens the safety of Mississippi's patients. HB 1317 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 HB 1317 crosses the line and puts Mississippi's patients at risk. Accordingly, we strongly urge you to oppose HB 1317.

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.** Indeed, 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 for which only physicians are trained. 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. As such, HB 1317 must be opposed.

HB 1317 is logistically impractical and a threat to patient safety.

The AMA is troubled by the breadth of this legislation. HB 1317 authorizes pharmacists to prescribe medications for "minor, nonchronic health conditions," including but not limited to unspecified "respiratory illness, condition, or disease," urinary tract infections, "skin conditions," and conditions that may be detected using a Clinical Laboratory Improvement Amendments (CLIA)-waived test. It authorizes pharmacists to treat patients of any age and with any pre-existing health condition. If enacted, HB 1317 would be one of the nation's broadest laws authorizing pharmacists to diagnose and treat—making Mississippi a dangerous outlier in terms of the provision of health care to its residents. The law 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, HB 1317 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 HB 1317.

Minor, nonchronic health conditions.

HB 1317 allows pharmacists to prescribe for "minor, nonchronic health conditions." While this term may seem benign on its face, it raises serious medical concerns. Namely, is the bill's failure to define "minor, nonchronic health condition," the bill gives pharmacists unfettered authority to prescribe for any condition ostensibly diagnosable as something the pharmacist does not immediately perceive as serious. This is deeply concerning because there are countless examples where severe life-threatening conditions can present as and be misdiagnosed as minor and nonchronic, especially by the untrained eye. Without a comprehensive 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 nonchronic," but one must ask how a pharmacist might know whether the lungs are clear without any training and without 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. It is dangerous to assume that an accurate diagnosis can be made over the pharmacy counter.

CLIA-waived tests.

HB 1317 also would allow 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 HB 1317 would permit pharmacists and pharmacy technicians to use these tests—all 1,500—to guide their clinical decision making and prescribe medications to patients based on the result. Logistically, it is unclear how CLIA-waived tests would be administered in a pharmacy setting.

Moreover, 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. 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.

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, HB 1317 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] Common sense dictates that scope expansions like the one proposed in HB 1317 only add burden to an overburdened pharmacist workforce and threaten patient safety and must be soundly defeated.

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[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

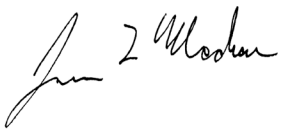
HB 1317 puts patients at risk.

As noted above and in closing, HB 1317 raises serious concerns. The AMA is deeply troubled with the overly broad, dangerous expansion of scope of practice afforded to pharmacists in HB 1317. We strongly urge you, along with members of the House Drug Policy Committee, to oppose HB 1317 because, simply put, patients in Mississippi 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: Mississippi State Medical Association