The Honorable John Thune Majority Leader United States Senate S-230, The Capitol Washington, DC 20510

The Honorable Mark Warner United States Senate 703 Hart Senate Office Building Washington, DC 20510

Dear Majority Leader Thune and Senator Warner:

The undersigned physician organizations representing national medical societies and state medical associations write in opposition to S. 2426, the "Equitable Community Access to Pharmacist Services Act (ECAPS) Act." Despite efforts to modify the text of this legislation in the 119th Congress, this bill still has numerous shortcomings, including inappropriately allowing pharmacists to perform services that would normally only be authorized and covered if they were furnished by a physician, testing and treating patients for certain illnesses and expanding Medicare payment for pharmacists in limited but significant ways.

This bill is focused on allowing pharmacists to perform Evaluation and Management services for influenza, COVID-19, respiratory syncytial virus (RSV), or streptococcal pharyngitis (strep throat). Evaluation and management services, however, constitute the practice of medicine and fall well beyond the scope of training of a pharmacist and, therefore, puts patient safety at risk. Unfortunately, S. 2426 includes additional provisions that allow these allied health professionals to engage in other activities that constitute the practice of medicine. More specifically, the undersigned organizations are concerned that the legislation includes provisions that permit the Secretary of the U.S. Department of Health and Human Services to authorize pharmacists to conduct testing and treatment for any services that "address a public health need related to [a] public health emergency declared under Section 319 of the Public Health Service Act." The undersigned organizations cannot in good conscience support any legislation that grants such an alarming and largely undefined expansion of clinical authority to a non-physician provider.

Our organizations strongly support the team approach to patient care, with each member of the team serving in a clearly defined role as determined by his or her education and training. While we greatly value the contribution of pharmacists to the physician-led care team and recognize that pharmacists are well-trained in activities like dispensing pharmaceuticals, advising patients on the use of medications, and understanding drug-to-drug interactions, pharmacists' training does not include performing a physical examination, diagnosing patients, or formulating a treatment plan. Furthermore, their training is substantially less extensive than that of physicians, who undergo four years of medical school, three to seven years of residency training, and 12,000-16,000 hours of clinical training. In contrast, pharmacists are required to complete only four years of education, no residency, and 1,740 hours of clinical training. As such, 95 percent of U.S. voters in a recent survey said it is important to them for a physician to be involved in diagnosis and treatment decisions. ¹

While pharmacists are well-trained as medication experts within an interprofessional team, their training in patient care is limited. Pharmacy students engage in a modest amount of "practice experiences" during their education, however, this training is not focused on providing medical care to patients. In fact, the practice experiences in the PharmD curriculum do not include performing a physical examination, making a diagnosis, triaging severity, or prescribing. Furthermore, neither the didactic nor practice experience

¹ https://www.ama-assn.org/system/files/ama-scope-of-practice-stand-alone-polling-toplines.pdf.

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component of a pharmacist's education prepares them to clinically assess patients or perform differential diagnoses to discern the root cause of a symptom. In short, pharmacists do not have the education and training necessary to diagnose and treat patients, all things that would be permitted under S. 2426, and it raises serious concerns about the underlying premise of this legislation.

We are particularly concerned that S. 2426 would permit pharmacists to evaluate and manage patients for the testing or treatment of COVID-19, influenza, RSV, or streptococcal pharyngitis. These diagnoses would be guided by the results of a CLIA-waived test, but this is problematic because the results of a test alone are not enough to make a conclusive diagnosis or to rule out other complications. For example, physicians are trained in residency to identify a serious illness, such as a respiratory disease, and to perform differential diagnoses; pharmacists simply are not. 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, and the underlying causes of symptoms may be overlooked.

Additionally, while the most recent version of this bill would require pharmacists to deliver this care within the confines of a collaborative practice agreement (CPA), it is unclear whether meaningful CPAs could be established in a community pharmacy setting. CPAs are typically established between a physician and a pharmacist working as part of a health system or a pharmacist embedded in a physician's office where the pharmacist provides drug therapy management services pursuant to protocol that is set forth by the physician based on the unique needs of the patient or patient population with whom the physician has a meaningful relationship. However, S. 2426 is focused on pharmacists practicing in the community setting. In these settings, it is likely that any CPA reached between a physician and community-based pharmacist would simply be perfunctory and not render true, meaningful collaboration. In addition, S. 2426 permits, in select circumstances, CPA agreements to be rendered between a pharmacist and a non-physician, thus leaving the physician completely out of the care team.

Equally concerning is the fact that pharmacists in the community setting said they already have so much work to do that everything cannot be done well.² The problem appears systemic with 71 percent of all pharmacists in a pharmacy chain setting and 91 percent of pharmacists working in community pharmacies rating their workload as high or excessively high. Moreover, pharmacists reported that their "three most common 'highly stressful' job aspects were 'having so much work to do that everything cannot be done well' (43 percent reporting 'highly stressful'), 'working at current staffing levels' (37 percent reporting 'highly stressful'), and 'fearing that a patient will be harmed by a medication error' (35 percent reporting 'highly stressful')."³ Scope expansions like the one proposed in this bill would only add further responsibilities to an overburdened pharmacist workforce and threaten patient safety due to their insufficient training in these activities.

Physician-led, team-based care has a proven track record of success in improving the quality of patient care, reducing costs, and allowing all health care professionals to spend more time with their patients. We are concerned that the policy changes within S. 2426 conflict with this approach to health care delivery and could result in patients forgoing holistic wellness exams, comprehensive preventive care, early diagnosis, and optimal therapy, which could have devastating long-term consequences.

Misdiagnoses, siloed and uncoordinated care, and patients not receiving the right care at the right time all lead to worse patient outcomes and add costs to our health care system. We should respect the success of

² https://www.bls.gov/ooh/healthcare/pharmacists.htm#tab-2.

³ https://www.aacp.org/sites/default/files/2020-03/2019 NPWS Final Report.pdf.

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coordinated physician led team-based care and put patient safety first by rejecting the misguided approach in this legislation. Therefore, we strongly encourage you to protect the health and safety of our patient population and oppose the passage of S. 2426.

Sincerely,