

November 18, 2024

The Honorable Ron Wyden
Chairman
U.S. Senate Committee on Finance
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
U.S. Senate Committee on Finance
Washington, DC 20510

Dear Chairman Wyden and Ranking Member Crapo:

The undersigned pharmacy organizations implore you to give meaningful consideration to our sincere and serious concerns regarding S. 3458/ H.R. 5526, the “Seniors’ Access to Critical Medications Act,” and respectfully request any ongoing Senate deliberation cease until the pharmacy industry is afforded the opportunity to provide input and counsel regarding the true and possibly detrimental impact of the legislation. This bill seeks to expand upon the in-office ancillary services exception to Stark law in significant ways. The bill raises important questions and concerns about how to protect state pharmacy licensure and/or medical practice dispensing laws as well as the limits of the Stark in-office ancillary services exception. It also raises important considerations about the practice of pharmacy and what pharmacy services are required and necessary to support patient access to quality care when drugs are shipped or sent by courier from a medical practice instead of being sent to the patient from a community, chain or specialty pharmacy. We firmly believe additional consideration of this legislation is needed to ensure the provision of high-quality patient care.

State Law - Pharmacy Licensure and Medical Board Approvals to Dispense

Pharmacy licensure is addressed at the state level primarily by State Boards of Pharmacy. In some states, medical boards are also permitted to approve physician practices to dispense medications; however, these boards do not issue pharmacy licenses. In addition, 30 of 50 states that allow physician dispensing for a Medical Doctor (M.D.) have additional state requirements or restrictions on direct dispensing to patients. The mailing of prescriptions by a physician practice has been restricted through the in-office ancillary services exception to Stark with only a brief waiver issued by the Department of Health and Human Services during the Public Health Emergency, which expired in 2023. Expansion of the Stark exception in a broader capacity to allow for pharmaceuticals to be couriered or mailed with limited physician-patient engagement raises questions as to whether allowing physicians to ship drugs would ever be in violation of or interfere with state pharmacy licensure and medical

dispensing laws, given the varied approach of state pharmacy-related licensure laws and the numerous physician dispensing models that exist today.

Post-Dispense Pharmacy Services, Standards and Accreditation

We strongly support the team approach to patient care. While pharmacists are medication experts trained and licensed to dispense pharmaceuticals, their training goes well beyond dispensing to support patient drug management and drug adherence. Pharmacies and pharmacists advise patients on the use of medications, assess for drug-to-drug interactions across drugs prescribed and provide medication management therapy. For many drugs, including complex specialty drugs for conditions like cancer and rheumatoid arthritis, the pharmacies that dispense these drugs are expected to meet accreditation standards, demonstrating they can manage all of the requirements associated with the use of a specialty drug, including:

- Cold chain management of a drug so that couriering or shipping of the drug does not jeopardize the integrity of the drug.
- 24-7 patient engagement and call center support to address patient concerns, toxicity risks and adverse events, especially with frequent dosage adjustments to manage complex conditions and therapies.

Furthermore, the legislation under consideration would permit physicians that dispense medications via mail or courier to not have to see a patient more than once a year. For many drugs, limited patient engagement would be dangerous and grossly insufficient to ensure patient safety and protect against adverse drug events.

Physician practices do not typically have the time or staffing to support all required pharmacy management activities once a drug is dispensed. Given the legislation's limitations, there is no oversight or standard to ensure they would provide any patient services associated with the drug after shipping it. With changes in federal law and to comply with the Food and Drug Administration (FDA), pharmacies are also required to prepare for meeting all FDA Drug Supply Chain Security Act (DSCSA) requirements for drugs dispensed within and outside of their pharmacies. We are not aware of any physician dispenser preparations to meet DSCSA requirements for drugs shipped outside of their practices.

Ensuring Against Anti-Competitive Activities and Practices

The in-office ancillary services exceptions to Stark law are meant to protect against anti-competitive market practices, including the seeking of personal financial gain at the expense of patient care. Under the proposed legislation, physicians would be permitted to continue as prescribers and dispensers and also mail medications, expanding their drug access and flexibilities. Such latitude could create an unfettered opportunity to capture market share and disadvantage independent and chain community and specialty pharmacies that are meeting the access needs of patients in underserved and rural communities today.

Conclusion

We are very concerned that failing to consider and address the potentially detrimental impact of this legislation at this time could lead to negative patient outcomes, adding significant costs to our health care system and anticompetitive market practices. It is imperative that we put patient safety at the forefront of any legislative decision making that impacts healthcare delivery and ensure pharmacy dispensing and post-dispensing management standards are always upheld by a dispenser, as required for community, chain and accredited specialty pharmacies today.

We strongly encourage you to protect the health and safety of our patient population and halt the advancement of S. 3458/H.R. 5526 at this time, allowing for dialogue and time to address our important concerns.

Sincerely,

American Pharmacists Association
FMI – The Food Industry Association
National Association of Boards of Pharmacy
National Association of Chain Drug Stores
National Association of Specialty Pharmacy