



*Unifying and strengthening the voice of pharmacy
while advancing pharmacy practice through
education, advocacy collaboration, and relationships*

March 25, 2020

The Honorable Ron DeSantis
Office of the Governor
400 S. Monroe Street
Tallahassee, Florida 32399

Re: Automated Pharmacy Dispensing Legislation (HB59)

Dear Governor DeSantis:

This correspondence is provided on behalf of the Florida Pharmacy Association, Inc. ("FPA"), a not-for-profit corporation organized under the laws of this state which seeks to preserve and advance the practice of pharmacy and serves the professional needs of all pharmacists, pharmacy students, and pharmacy technicians in Florida. The FPA is the state's largest and oldest professional society representing Florida pharmacists and pharmacies with over 3,500 members. The FPA is committed to improving public health and patient care, enhancing professional development, and advocating for the interests of the profession. The purpose of this letter is to notify the Executive Office of the Governor of the FPA's serious concerns with CS/CS/HB 59 – Automated Pharmacy Systems (the "Bill") and to respectfully request that the Governor veto the Bill.

Currently, pharmacies are authorized to provide pharmacy services to long term care facilities, hospices, and state correctional institutions through the use of automated pharmacy systems located at such facilities. The Bill, passed by the Legislature on March 13, 2020, significantly expands the use automated pharmacy systems. The Bill authorizes community pharmacies to provide pharmacy services through automated pharmacy systems "housed in an indoor environment area and in a location to increase patients' access to their prescriptions, including, but not limited to, medical facilities or places of business where essential good and commodities are sold or large employer workplaces or locations where access to a community pharmacy is limited." CS/CS/HB 59 at lines 34-39.

Many aspects of the Bill were points of contention between the proponents and opponents of the Bill, but none more so than the location of the automated pharmacy systems. The Bill allows for automated pharmacy systems to be located in any indoor environment area in a location to increase patient access to prescriptions. The Bill does not define “indoor environment area” or “location to increase patient access to their prescription”. It also does not provide the Board of Pharmacy (the “Board”) with rulemaking authority to determine where the systems may be located. It is our belief that the extremely broad language of the Bill allows the systems to be located inside any building anywhere in the State of Florida.

This is at odds with what the Bill’s proponents stated was the intent of the Bill. Throughout the legislative process, the Bill’s proponents indicated that the Bill “limits” where automated pharmacy systems can be located. Proponents stated that the Bill does not allow for the “broad” deployment of these systems across the state. However, as noted, this is contradicted by the plain language of the Bill. The Bill allows for these systems to be placed at any indoor environment area that increases patient access to prescriptions. Of course, any location would increase access to prescriptions for at least one patient.

Furthermore, proponents stated that the Bill gives the Board rulemaking authority to determine suitable locations for automated pharmacy systems. To the contrary, the Bill does not provide the Board with authority to adopt rules restricting locations where automated pharmacy systems may be placed. The Bill provides the Board of Pharmacy with the following rulemaking authority:

(6)The board may adopt rules governing the use of automated pharmacy systems. If adopted, such rules must include all of the following:

(a) Recordkeeping requirements.

(b) Security requirements.

(c) Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:

1. The dispensing pharmacy.
2. The prescription number.
3. The name of the patient.
4. The name of the prescribing practitioner.

Id. at lines 131-145.

Initially, it should be noted that the Bill does not even require the Board to adopt any rules to implement the Bill. The Bill says that the Board “may” adopt rules. However, if the Board does elect to adopt rules, such rules may only address the “use” of the systems, and must include recordkeeping requirements, security requirements, and labeling requirements. This does not give the Board the authority to adopt rules that, for example, prohibit automated pharmacy systems from being located in a gas station or at an indoor kiosk in a parking lot. See §120.52(8), Fla. Stat. (“An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation....”)

With that said, we acknowledge that the Board has the authority to establish security requirements for automated pharmacy systems. We believe this could allow the Board to establish requirements for structures which house the systems to ensure that that systems are secure. However, we do not believe the rule could place a restriction on the types of businesses or locations which can house the systems as this would exceed the Board’s authority. Thus, the Bill allows for the systems to broadly deployed throughout the state, contrary to the proponents’ stated intention.

Additionally, the Bill requires that an automated pharmacy system must be under the supervision and control of a community pharmacy (although later in the Bill it provides that the system must be under the supervision of a pharmacist). Id. at lines 32-33, 114-166. The Bill does not provide any guidance as to how many systems a pharmacy or pharmacist may supervise at any given time or where the supervising pharmacy or pharmacist must be located. When these issues were raised, the Bill’s proponents indicated that the Board could address the issues through rulemaking.

As noted above, the Bill provides the Board with limited rulemaking authority. A rule establishing limits on the number of systems a pharmacy/pharmacist can supervise at any given time or the location of the supervising pharmacy/pharmacist is not related to the “use” of the system or recordkeeping, security, or labeling requirements and, therefore, would exceed the Board’s rulemaking authority. The lack of any restriction on the number of systems a pharmacy/pharmacist can supervise eliminates any meaningful supervision of the systems as pharmacies/pharmacists could potentially oversee thousands of systems at any given time. Further, the supervising pharmacies/pharmacists could be thousands of miles from Florida while conducting this “supervision”. These systems should not be allowed to operate throughout the state without any meaningful oversight.

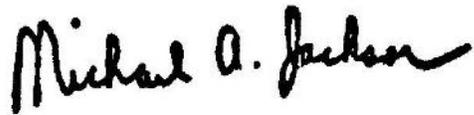
Finally, this Bill will have a detrimental impact on independent pharmacies. The Bill authorizes automated pharmacy systems to dispense medications that are not controlled substances. The policy behind this is wise. However, this brings automated pharmacy systems in direct competition primarily with independent pharmacies. Approximately 80% of the medications dispensed by independent pharmacies in Florida are not controlled substances. Flooding the state with these systems will likely result in the closure of many independent pharmacies.

The Bill’s lack of rulemaking authority will hinder the Board’s ability to establish the guardrails needed to ensure that automated pharmacy systems are safe and effective. Each time we raised these issued during

the legislative process we were assured that the Board would be able to address the issues through rulemaking. However, as discussed above, the Bill fails to include the necessary authority to ensure that the Board can fulfill its mandate of protecting the public health, safety, and welfare and will harm independent pharmacies. For these reasons, we respectfully request that the Governor veto the Bill.

Thank you for your time and consideration and please do not hesitate to contact me should you have any questions.

With kindest regards,



Michael A Jackson, BPharm, CPh
Executive Vice President and CEO

