PRIVILEGED AND CONFIDENTIAL

M E M O R A N D U M

TO: Lora Miller, Ohio Council of Retail Merchants

FROM: Robin L. Canowitz, Jolie Havens, Nikkia Knudsen

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RE: Analysis of Issues related to H.B. 324

The Ohio Council of Retail Merchants has asked Vorys to summarize health care issues and implications related to H.B. 324 (the "Bill"), which we have outlined below. The Bill, also known as the Patient Protection Act, seeks to regulate the sale and prescription of drugs causing severe adverse effects in more than 5% of users. The Bill, as currently written, may result in various unintended, negative consequences. If you would like to discuss further, need follow-up, or if you have any questions, please let us know. We are happy to assist as needed on this or other matters.

1. **The Bill presents material ambiguities.**

As referenced, the Bill prohibits a retailer (including Ohio retail pharmacies) or a terminal distributor of dangerous drugs (including many other Ohio health care providers) from offering to sell or selling a drug via mail or over the counter without a prescription if the drug causes one or more severe adverse effects in greater than 5% of users. The bill does not specify what the group of "users" encompasses. It is unclear if it applies only to Ohio users, or all users of the drugs. The Director of the Ohio Department of Health, in collaboration with the Superintendent of the Ohio Department of Insurance and the Executive Directors of the State Board of Pharmacy and State Medical Board, is tasked with determining whether a drug meets this criterion. The determination will be based on insurance claims, patient reports of severe adverse effects to healthcare professionals, and relevant data from the United States Food and Drug Administration (FDA). However, the Bill does not specify how the total number of users is to be calculated (or would ever be reliably tracked), leading to potential uncertainty on which drugs will be subject to this prohibition. Further, there is no guidance provided regarding how "patient reports of severe adverse effects" would be tracked and analyzed by the group tasked with making this determination. Additionally, the bill does not provide any way for citizens or health care providers

to challenge these decisions, or for the group making these determinations to re-evaluate their decisions if more information regarding these drugs comes to light. Accordingly, the lack of guidance on this determination process could lead to over-inclusiveness in the list of restricted drugs, thereby depriving Ohioans of their ability to obtain desired medications within the state which are otherwise deemed appropriate and safe by existing regulators charged with review of such matters.

Moreover, if passed as written, the lack of guidance on the drug determination process makes H.B. 324 ripe for void-for-vagueness challenges. Essentially, laws are required to provide fair notice of prohibited conduct to avoid due process violations.[1] Here, as discussed above, there is no guidance for who would constitute a "user" and how drugs subject to the regulation would be determined based on data base criteria. As such, a person of ordinary intelligence would not be able to reasonably determine which drugs would be subject to the prescribing practices.

2. **The Bill is extremely broad, incorporating some of the most currently prescribed medications and creating barriers to care and medication access.**

The Bill, as currently drafted, is exceedingly broad and may encompass some of the most frequently prescribed medications. Specifically, the definition of "drug" includes both over-the-counter medications (which, notably, do not require a prescription) and dangerous drugs (which do require a prescription). Additionally, "severe adverse effects" is expansively defined to include any of the following: death, infection requiring hospitalization, hemorrhaging requiring hospitalization, organ failure, or sepsis.

In testimony provided by Representative Adam Mathews on June 11, 2025, Representative Mathews acknowledged that certain critical drugs, such as cancer medications, would meet the thresholds proposed in the Bill. However, he noted that cancer patients are already managed with consistent oversight from oncologists, but it is not clear whether this somehow excepts such medications from the Bill, as use of most medications (and certainly all prescription medications) are used with some level of professional supervision by a health care provider. Further, the testimony also does not address how the broad definitions will regulate a variety of other commonly prescribed drugs, some of which may not require consistent oversight from a health care professional in the same way as cancer drugs do, including, for example, Plavix, Wellbutrin, Metformin, Atorvastatin, Amoxicillin, and Ibuprofen.

The Bill may create significant barriers to medical care and medication access. Specifically, the Bill imposes additional requirements on prescribers before they can prescribe the

[1] *See generally*, *Belle Maer Harbor v. Charter Twp. of Harrison*, 170 F.3d 553 (6th Cir.1999); *State v. Kisil*, 2024-Ohio-2441, 246 N.E.3d 963 (6th Dist. 2024). Note that success on a void for vagueness argument is variable and extremely context-dependent, depending on the rights impacted as well as the specificity of such a challenge. Here, without a final proposed Bill, it is difficult to ascertain the success of such a challenge to the Bill.

restricted drugs, including mandatory in-person examinations and follow-up appointments. This requirement would apply to commonly prescribed drugs, such as Atorvastatin, which is considered a maintenance drug. Such stipulations create obstacles for patients who may not be able to readily access a healthcare provider for appointments, especially in areas where provider care is already limited, such as rural regions in which critical health care services are bolstered by the permissible use of telehealth. These requirements would further exacerbate existing barriers faced by patients with limited mobility, financial constraints, and/or transportation issues.

Importantly, the Bill would prohibit a retail pharmacy from selling an over-the-counter drug without a prescription if the drug causes severe adverse effects in 5% or more of users. As referenced above, Ibuprofen potentially falls within this broad definition. Presumably, under this Bill, if a patient wanted an over-the-counter medication that was banned, a patient would now need to obtain a prescription in order to purchase that over-the-counter drug. Requiring a prescription for common over-the-counter drugs would significantly reduce consumer access to these medications, especially in situations where the FDA has already made a determination that a medication is safe to be sold over-the-counter. Further, it would add additional strain on retail pharmacies which would now be required to take additional time to dispense drugs that are currently readily available without the need for a prescription. Additionally, this prescription requirement would further strain healthcare providers, who would be obligated to conduct in-person examinations and follow-up appointments for commonly used over-the-counter drugs, such as Ibuprofen. Providers would understandably seek to bill insurers and other third-party payors (like Medicare and Medicaid) for such services, further increasing health care costs unnecessarily and driving up the cost of insurance and other health coverage. Further, it is doubtful that a trip to a medical provider to obtain an over-the-counter drug, such as Ibuprofen, would be considered medically necessary and qualify for payment under most health plans. If not, then providers would be providing services for which they won't be paid, and for which, in many instances, they would be prohibited from billing the patient directly.

Additionally, the Bill prohibits any mail-order sales of any drug that meets the specified threshold. Patients, particularly those in rural areas, already face significant barriers to medication access, which mail-order prescriptions help to mitigate. Such a prohibition would adversely affect individuals who rely on mail-order pharmacies, which are often crucial in rural or underserved areas. This Bill arguably also implicates the ability to purchase over-the-counter medications from online platforms like Amazon, Door Dash, and Instacart. Without access to necessary medications, patients experiencing these barriers may suffer further declines in their health which are completely unnecessary.

Furthermore, despite the Bill's extensive implications, it fails to provide any exceptions to address the resulting barriers to care and medication access. Notably, as referenced, common drugs, such as over-the-counter pain relievers, could be subject to the prescription requirement without any exceptions. Additionally, patients who require life-saving medication, but reside in

rural areas, will be unable to access medication as needed via mail. The absence of any exceptions virtually ensures that existing barriers to care and medication access will be exacerbated.

If enacted, the Bill would empower a select group of individuals to determine which drugs should be subject to the restrictions. Essentially, a few unelected officials would have the authority to make decisions affecting a large number of individuals. The impact of these decisions would disproportionately affect those in already underserved areas, exacerbating existing barriers to care and further impacting the health of Ohioans.

3. The Bill creates potential conflicts with existing Ohio laws.

The Bill directly conflicts with existing Ohio telehealth requirements, which permit certain practitioners to prescribe medications via telehealth without requiring in-person consultations.[2] As referenced, the Bill mandates in-person examinations and follow-up appointments for any drugs that have serious adverse effects in more than 5% of users. This requirement is at odds with current Ohio telehealth laws, which allow practitioners to prescribe both controlled and noncontrolled substances via telehealth without an in-person visit, as permitted under state and federal law.[3]

While Ohio practitioners may prescribe medications to established patients, the Bill would require them to conduct a physical examination of new patients before prescribing any Schedule II controlled substances, unless an exception applies.[4] Despite this limitation, the Bill remains in conflict with telehealth laws by necessitating in-person examinations for ***any drug***, including over-the-counter and prescription medications, that cause serious adverse effects in 5% or more of users.

The Bill also directly conflicts with Ohio law's automatic incorporation of changes to the federal drug schedules.[5] Specifically, changes to the prescribing requirements for over-the-counter drugs arguably alters the federally established schedule classification. Since the federally established schedule classification is automatically incorporated into state law, the Bill would conflict with current state law.

Further, the Bill has the potential to conflict with current regulations relating to prescribing requirements for specific professionals. For example, physicians are required to comply with all applicable provisions of federal law governing the possession, distribution, or use of controlled substances.[6] As described above, the Bill would conflict with federal drug classifications, potentially compelling physicians to act in non-compliance with federal laws governing the

[2] *See* Ohio Admin. Code § 4731-37-01; Ohio Admin. Code § 4731-11-09.
[3] *See id.*
[4] *See* Ohio Admin. Code § 4731-11-09(D).
[5] *See* Ohio Rev. Code § 3719.43.
[6] *See* Ohio Admin. Code § 4731-11-02.

possession, distribution, or use of controlled substances. This non-compliance would, in turn, arguably constitute a violation of Ohio law.

4. The Bill conflicts with existing federal laws and standards.

In addition to actual and potential conflicts already mentioned, the Bill conflicts with federal laws. While state law can be more stringent than federal law, it cannot directly conflict with federal law. Federal law is the highest authority; therefore, federal law supersedes or supplants any state or local statute or regulation that conflicts with it. This doctrine comes from the Supremacy Clause of the United States Constitution.[7]

Currently, the proposed Bill would conflict with federal laws regulating the prescribing and dispensing of drugs. However, the question remains as to whether the proposed Bill is simply more stringent than federal law, which is permissible. If so, the Bill may not be preempted by federal law, provided that regulated entities and individuals can comply with both state and federal law. Generally, the FDA and the Drug Enforcement Agency ("DEA") establish safety, efficacy, labeling, and prescribing requirements for drugs. Specifically, the Controlled Substances Act[8] grants the DEA the authority to regulate the manufacturing, distribution, and dispensing of controlled substances and categorizes drugs into the appropriate schedule classification.[9] Similarly, the federal Food, Drug, and Cosmetic Act ("FDCA")[10] grants the FDA authority to regulate the approval, labeling, and marketing of over-the-counter drugs and prescription medications. Additionally, the recent Ryan Haight Online Pharmacy Consumer Protection Act of 2008 amended the CSA by adding several provisions related to the legal distribution and dispensing of controlled substances.[11]

As referenced, the Bill would conflict with some of the aforementioned requirements, making current prescribing and dispensing practices allowable under federal law prohibited under Ohio law. In fact, the Bill analysis itself references that the FDA has the authority to regulate drug sales and recalls and, as such, the Bill would prompt serious preemption questions.[12] Further, the Bill attempts to preempt decisions already made by the FDA related to drug safety, and impose a different standard to evaluate the safety of both prescription and non-prescription drugs in Ohio. Nonetheless, it is at least theoretically possible that the Bill could be interpreted as merely implementing more stringent prescribing standards for Ohio. For example, the Bill necessitates in-person exams for prescribing over-the-counter medications which could include drugs such as

[7] *See* U.S. Const. Art. VI., § 2.
[8] *See generally*, Title 21 Chapter13 of the United States Code.
[9] Interestingly, it seems as though cannabis is not contemplated under H.B. 324 as it is currently written. However, incorporation into H.B. 324 would present additional federal and state conflicts.
[10] *See generally*, Title 21 Chapter 9 of the United States Code.
[11] *See generally*, Title 21 Chapter13 of the United States Code.
[12] Ohio Legislative Service Commission, H.B. 324, 136th General Assembly Bill Analysis (June 3, 2025).

Ibuprofen, which the FDA has approved for over-the-counter use. A court could determine that entities and individuals can comply with both state and federal law, as the state law is simply imposing a higher standard for over-the-counter drugs rather than prohibiting dispensing altogether. Essentially, the argument would be that compliance with both is achievable by taking an extra step in Ohio – e.g., conducting the required in-person exams before prescribing these medications.

Federal case law has consistently addressed the extent to which states can establish stricter laws or regulations in areas where federal law also operates. Specifically, courts have examined whether state laws conflict with federal statutes, whether they intrude on fields exclusively governed by federal law, and whether they stand as obstacles to the objectives of Congress. In *Tibbe v. Ranbaxy, Inc.*, 2017-Ohio-1149 (1st Dist.), the court affirmed the lower court's determination that state requirements that would require generic drug manufacturers to provide additional or different warning labels on drugs were clearly preempted by federal law. The Court reasoned that conflict preemption had been established because drug manufacturers were unable to comply with both the federal and state law requirements. Generally, conflict preemption is established when a party cannot satisfy its state duties without the federal government's special permission and assistance.[13] Here, it seems unlikely that parties would be completely unable to comply with the Bill without approval by the federal government. As such, it is possible that a court could determine that conflict preemption would not apply and such challenges to the Bill would fail.[14] That said, historical authority and purview on these issues rests with the federal government.

Recently, in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), the U.S. Supreme Court was presented with a challenge to the FDA's approval and regulation of mifepristone, a medication used in medication abortions. The question posed was whether the FDA appropriately approved the drug and the subsequent regulations that allowed the drug to be dispensed via mail. The Supreme Court punted on the plaintiffs' challenge to the FDA's actions and instead determined that the plaintiffs failed to establish Article III standing, a constitutional requirement for bringing a case in federal court. As a result, the challenge to the FDA's regulatory actions was dismissed, leaving open the question as to whether the FDA has authority to authorize the mailing of drugs. We suspect a similar issue may be percolating here, and the Bill could be a further attempt to get the Supreme Court to eventually weigh on this or similar issues.

Notably, as previously referenced, Ohio law automatically incorporates changes to federal drug schedules in the context of controlled substances.[15] This practice reflects a form of preemption, whereby state law is consistently aligned with federal drug regulations. Under the

[13] Tibbe, 2017-Ohio-1149 at 843.
[14] Like void for vagueness, without a final proposed Bill, it is difficult to ascertain how the courts would interpret preemption challenges to the Bill.
[15] *See* Ohio Rev. Code § 3719.43.

proposed Bill, the change in practices would directly contradict these federal drug regulations. Given Ohio law's historical alignment with federal standards, there is a stronger argument that the Bill could be preempted in this context (or should be based on historical practices and precedent).