PRIVILEGED AND CONFIDENTIAL

M E M O R A N D U M

TO: Lora Miller, Ohio Council of Retail Merchants

FROM: Jolie N. Havens, Robin L. Canowitz, and Jordan Z. Kulbarsh

DATE: April 29, 2025

RE: Vorys' Analysis of Issues Related to H.B. 12

I. Introduction and Overview

The Ohio Council of Retail Merchants has asked the Vorys law firm to analyze potential issues related to Ohio H.B. No. 12 ("H.B. 12") as recently proposed by the 136th General Assembly.[1] With this goal in mind, we have identified and summarized below the issues that will have the greatest impact on Ohio retail pharmacies and pharmacists.

Specifically, this memorandum begins with a discussion on matters that are novel to H.B. 12. The memorandum then moves into an analysis of the issues that were previously identified in Ohio Sub. H.B. 73 ("Sub. H.B. 73") and how such issues may have been addressed or have evolved.[2] After analyzing the issues identified in previous iterations of the bill, this memorandum will conclude with a brief overview of the issues H.B. 12 poses for hospitals and inpatient facilities.

II. Issues Novel to H.B. 12

As discussed below, H.B. 12 has added or revised certain language that is of great consequence and should be of great concern to Ohio retail pharmacies, pharmacists, and other health care industry stakeholders. These changes exacerbate many of the issues that were raised regarding Sub. H.B. 73 as passed by the House, and create further confusion, conflict, and potential liability for retail pharmacies and pharmacists.

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[1] *See* H.B. No. 12, 136th Gen Ass. (Oh. 2025) (pending). This legislation has been named the Jeff, Dave, and Angie Patient Right to Try Act (the "Right to Try Act").
[2] *See* Sub. H.B. No. 73, 135th Gen Ass. (Oh. 2024).

1. The Applicability of H.B. 12 to the Prescribing, Dispensing, and Administering of *All* Drugs

Unlike how Sub. H.B. 73 more narrowly applied to the prescribing of drugs for *off-label use*, H.B. 12 applies to the prescribing, dispensing, and administering of drugs for *any use* unless certain other laws apply.[3] Therefore, H.B. 12 can now be interpreted to mean that:

- *Any drug, including a drug for off-label use*, may be prescribed to a patient if the prescriber has obtained the informed consent of the patient or the patient's personal representative.[4]

- *Any drug, including a drug for off-label use*, shall be dispensed by a pharmacist, hospital, or inpatient facility unless the pharmacist (a) has a moral, ethical, or religious objection that conflicts with the drug's dispensing consistent with O.R.C. § 4743.10 or (b) the pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the drug or there is a life-threatening contraindication.[5]

- When neither of the exceptions in O.R.C. § 3792.08(C)(1) apply, in order to obtain immunity from certain potential liability, a pharmacist, pharmacy, hospital, or inpatient facility with an objective, good faith, and scientific objection to the administration or dosage of *any drug, including a drug for off-label use*, must explain and discuss the objection with the prescriber, and as soon as practicable and within twenty-four hours after dispensing, the pharmacist, pharmacy, hospital, or inpatient facility must document in the patient's medical record that the objection was explained and discussed with the prescriber before dispensing.[6]

- Except as provided in narrow circumstances listed in O.R.C. § 3792.08(G), a health-related licensing board (such as the Ohio Board of Pharmacy), the Ohio Department of Health, or another state agency responsible for the licensure or regulation of health care professionals or health care facilities shall not consider the action of prescribing, dispensing, or administering *any drug, including a drug for off-label use*, to a consenting patient or with the informed consent of the patient's personal representative, by a prescriber, pharmacist, pharmacy, hospital, or inpatient facility under O.R.C. § 3792.08 to be unlawful, unethical, unauthorized, or unprofessional conduct and shall not pursue professional discipline or fines or other regulatory sanctions against the

[3] *See* H.B. No. 12 *supra* note 1, at 1. H.B. 12 seeks to enact section 3792.08 of the Ohio Revised Code. While this bill has not yet been enacted into law, we will refer to specific provisions of this bill in this memorandum through reference to O.R.C. § 3792.08.
[4] *See* O.R.C. § 3792.08(B).
[5] *See* O.R.C. § 3792.08(C)(1).
[6] *See* O.R.C. § 3792.08(C)(2).

> prescriber, pharmacist, pharmacy, hospital, or inpatient facility, except in cases where prescribing, dispensing, or administering the drug to the patient was done with recklessness or gross negligence.[7]

In short, H.B. 12 creates additional obligations for pharmacists and pharmacies when they dispense *all drugs* – not just when they dispense drugs for off-label use as was originally proposed in Sub. H.B. 73. This is a major issue because the clinical, professional, and ethical conflicts posed in Sub. H.B. 73 will no longer be confined to the dispensing of drugs for off-label use only, but instead, will present themselves literally any time a pharmacist/pharmacy dispenses a drug in Ohio, whether the drug is for on- or off-label use. This change is a significant overreach based on the previously stated purpose of the legislation.

2. The Carveouts Specified in H.B. 12

i. Who the Carveouts Do and Do Not Apply To

As referenced above, H.B. 12 has carved out certain instances when its mandates do not control. Notably, a prescriber may not issue a prescription for any drug as required under H.B. 12, including a drug for off-label use, when otherwise provided in O.R.C. Chapters 4715, 4723, 4725, and 4730 or in compliance with other state law regarding prescribing drugs.[8] The issue, however, is that none of the identified chapters apply to retail pharmacies and pharmacists.[9] As a result, H.B. 12 applies to all pharmacists (and pharmacies) who are not traditional prescribers.

In limited instances, however, pharmacists are permitted to administer drugs, add drugs to a patient's drug therapy, or even discontinue the use of prescribed drugs.[10] These actions can be taken pursuant to "Consult Agreements," as established in O.R.C. § 4729.39, between pharmacists and physicians, physician assistants, or advanced practice registered nurses.[11] Nevertheless, because Chapter 4729 is not specifically identified in H.B. 12, it is, at best, unclear whether this chapter is carved out of the bill, which it does not appear to be. As a result, consulting pharmacists may be required to act under H.B. 12 in a manner that contradicts their obligations under their consult agreements. For example, while a consult agreement must state the diagnosis being managed under the agreement for a pharmacist to administer, add, or discontinue the use of a drug, H.B. 12 requires pharmacists to dispense drugs regardless of whether a diagnosis has been made for a patient. This is an open issue under H.B. 12.

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[7] *See* O.R.C. § 3792.08(E).
[8] *See* O.R.C. § 3792.08(B).
[9] The Chapters for which prescribing rules supersede the rules set forth in H.B. 12 apply to dentists (Chapter 4715), nurses (Chapter 4723), optometrists (Chapter 4725), and physician assistants (Chapter 4730).
[10] *See* O.R.C. § 4729.39(D)(1)(a).
[11] *See* O.R.C. § 4729.39(B).

Furthermore, unless related to free speech, as described in O.R.C. § 3792.08(F), H.B. 12 states that it does not apply to, repeal, or supersede existing law regarding prescribing, dispensing, or administering any of the following:

- Controlled substances, including opioids;
- Drugs subject to a United States food and drug administration ("FDA") risk evaluation and mitigation strategy;
- Cross-sex hormones or puberty-blocking drugs, as defined in O.R.C. § 3129.01, to be used in violation of O.R.C. § 3129.02;
- Abortifacients when prescribed, dispensed, or administered to patients who are known to be pregnant; or
- Drugs that are known to be used for the intent or purpose of euthanasia.[12]

Once again, none of these carveouts have any bearing on the clinical, professional, or ethical obligations of Ohio pharmacists and pharmacies. Instead, this bill simply indicates that drugs deemed "undesirable" from a public policy standpoint should not be awarded the same latitude and "rights" every other drug would now be awarded in Ohio, except for controlled substances and drugs subject to an FDA risk evaluation and mitigation strategy. Therefore, even though certain carveouts have been identified, H.B. 12 still fails to protect Ohio pharmacies' and pharmacists' ability to comply with their clinical, professional, and ethical obligations under contrasting state and federal law.

ii. The Carveout's Impact on the Ohio Automated Rx Reporting System

By carving out controlled substances from the bill, H.B. 12, generally, no longer requires pharmacists to act in ways that violate their duties under the Ohio Automated Rx Reporting System ("OARRS"). As discussed in our previous analysis, OARRS is a tool maintained by the Ohio Board of Pharmacy designed to monitor dispensing and prescribing information for suspected abuse or diversion (such as channeling drugs into illegal use) and is a tool that can give a pharmacist (as well as a prescriber) critical information regarding a patient's controlled substance prescription history.[13] As a result, OARRS helps pharmacists (and prescribers) identify high-risk patients who would benefit from early interventions.

Specifically, existing law requires pharmacists to request and review an OARRS report, covering at least a one-year time period, when:

- The patient adds a different or new controlled substance or a drug containing gabapentin to their therapy that was not previously included;

[12] *See* O.R.C. § 3792.08(G).
[13] *See* Ohio Board of Pharmacy, About – What is OARRS?, https://www.ohiopmp.gov/About.

- An OARRS report has not been reviewed for the patient in the prior 12 months;
- The prescriber is located outside of the usual pharmacy geographic area;
- The patient is located outside of the usual pharmacy geographic area;
- The pharmacist has reason to believe the patient received prescriptions for controlled substances or a drug containing gabapentin from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location; or
- The patient exhibits signs of potential abuse or diversion.[14]

Ultimately, a pharmacist may decline to dispense a prescription when the pharmacist determines that dispensing the prescription is not appropriate based on information contained in a patient's OARRS report, if an OARRS report is not immediately available, or the prescription is not able to be dispensed based on other aspects of the pharmacist's required prospective drug utilization review.[15] This required review and the implementation of the OARRS system on the whole are part of several steps taken by the State of Ohio to combat the abuse and diversion of controlled substances.

Nevertheless, Sub. H.B. 73 ignores these existing mandates related to OARRS by requiring pharmacists to dispense drugs for off-label use – including controlled substances – unless the pharmacist can meet one of the limited exceptions set forth in the bill. None of these exceptions, however, provide additional time for pharmacists to meet their obligations under OARRS. Fortunately, H.B. 12 now expressly states that the bill does not "apply to, repeal, or supersede existing law regarding prescribing, dispensing, or administering" controlled substances, including opioids.[16] As a result, H.B. 12 now permits Ohio pharmacists to observe their OARRS obligations for controlled substances even when they may otherwise contrast with the requirements set forth in the bill.

However, it is very important to recognize that H.B. 12 is completely silent when it comes to gabapentin and naltrexone (when prescribed for substance use disorder treatment), the two non-controlled substances that currently fall within the purview of OARRS (a list which potentially could be expanded in the future by the Ohio Board of Pharmacy).[17] Therefore, while pharmacists would seemingly be permitted to continue following their obligations under OARRS when a controlled substance is prescribed, it is unclear, and seems unlikely, that pharmacists would be permitted to complete and comply with all of their obligations under OARRS when gabapentin or naltrexone is prescribed, as there are inherent conflicts between a pharmacist's OARRS obligations and H.B. 12 mandates. Hence, while H.B. 12 has alleviated some of the tensions that Sub. H.B. 73

[14] *See* O.A.C. 4729:5-5-08(D).
[15] *See* O.A.C. 4729:5-5-08(C), (E), and (G); *see also* O.A.C. 4729:5-5-10(A); *see also* O.A.C. 4729:5-5-15.
[16] O.R.C. § 3792.08(G)(1).
[17] *See* About – What is OARRS?, *supra* note 13 (explaining that OARRS applies to all controlled substances and the two non-controlled substances gabapentin and naltrexone).

had with OARRS, H.B. 12 has failed to fully address all apparent conflicts with the OARRS program. Such a critical lapse in drafting makes it easier for high-risk. non-controlled substances like gabapentin and naltrexone to be abused and diverted into the wrong hands and creates potential clinical, professional, ethical, and liability concerns for Ohio pharmacists and pharmacies.

III. Issues Present in H.B. 12 That Remain from Sub. H.B. 73

A number of the issues that we highlighted in our previous analyses of Sub. H.B. 73 remain in H.B. 12. With that being said, drafting changes have altered some of these areas of concern so that they may take on a new form. As a result, while portions of the following discussion are similar to our previous analyses, other portions of the discussion serve to identify where changes have been made to the bill and discuss the impact that those changes may have on retail pharmacies and pharmacists.

1. The Failure to Reconcile the Requirements of H.B. 12 with the Existing Professional Obligations of Pharmacists

Perhaps the most notable issue that has persisted from Sub. H.B. 73, the requirements of H.B. 12 continue to directly conflict with Ohio pharmacists' existing obligations to determine the legitimacy of and to exercise their professional judgment when dispensing, or under certain circumstances, declining to dispense, prescriptions. More specifically:

- O.A.C. § 4729:5-5-15(A) states that pharmacists can only dispense a prescription if it is issued for a legitimate medical purpose by a prescriber acting in the normal course of the prescriber's practice. While responsibility for properly prescribing the medication is placed upon the prescriber, a corresponding responsibility rests with the pharmacist to appropriately dispense the prescription. As a result, when an order purported to be a prescription is not issued in the normal course of the bona fide treatment of a patient, any pharmacist who knowingly dispenses such a purported prescription will be subject to sanction.[18]

- O.A.C. § 4729:5-5-08(G) prohibits pharmacists from dispensing a prescription when it is of doubtful, questionable, or suspicious origin, as determined by the pharmacist.[19]

- O.A.C. § 4729:5-5-10(G) prohibits pharmacists from dispensing a prescription of a dangerous drug if it is too old, even if refills are remaining. Instead, new prescriptions must be filled for the first time within six months from the date of issuance of the prescription.

[18] *See* O.A.C. 4729:5-5-15(A); *see also* O.A.C. 4729:5-5-15(A).
[19] *See* O.A.C. 4729:5-5-08(G).

> Refills, if any, for non-controlled substances only remain valid for one year from the date the prescription was written, with greater limitations on the refill of controlled substances.[20]

Ignoring these and other existing mandates, H.B. 12 requires that pharmacists dispense drugs to a patient when prescribed, even when the pharmacist has an objective, good faith, and scientific objection to dispensing the prescription, except where the pharmacist (a) has a moral, ethical, or religious objection with dispensing the drug consistent with O.R.C. § 4743.10 or (b) the pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the drug (which a pharmacist may not necessarily know about even when such circumstances exist) or there is a life threatening contraindication.[21]

The direct conflict in the law created by H.B. 12 is completely unworkable because it would be impossible for pharmacists to comply with both the requirements of H.B. 12 as well as their existing legal obligations outlined above. In other words, H.B. 12 effectively negates a pharmacist's professional judgment and could require, among other things, the dispensing of illegitimate, questionable, or old prescriptions, which could be very harmful to individual patient safety and the community as a whole. Furthermore, while the bill purports to provide some level of immunity from civil liability and professional discipline to pharmacists for compliance with H.B. 12, such immunity does not expressly extend to a pharmacist's failure to comply with other conflicting legal mandates which the pharmacist is subject to.[22]

Lastly, when a pharmacist does have an objective, good faith, and scientific objection to dispensing a prescription and is required to dispense it regardless, in order for immunity to attach, the pharmacist must document the objection in the patient's medical record.[23] As noted in our previous analysis on Sub. H.B. 73, this requirement creates an additional, unnecessary obligation for pharmacists to adhere to. Unlike Sub. H.B. 73, however, H.B. 12 requires pharmacists to also explain and discuss their objection with the prescriber prior to documenting such an objection into the patient's medical record.[24] A practical question also exists as to whether pharmacists in a retail setting would actually have the ability to document such objection in the "medical record" of the patient, as the systems used by retail pharmacists may not allow for such documentation to occur, or have a place where pharmacists could fully document their objections as contemplated here.

This new requirement to discuss a pharmacist's objection with the prescriber is an issue for two main reasons. For one, it is yet another unnecessary obligation that thwarts pharmacists from performing their job in an efficient manner. While such discussions may happen now organically when circumstances warrant, H.B. 12 creates a new obligation, exacerbated by the application of

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[20] *See* O.A.C. 4729:5-5-10(G); *see also* O.A.C. § 4729:5-5-15(B)(8)–(11).
[21] See O.R.C. § 3792.08(C)(1).
[22] *See* O.R.C. § 3792.08(C)(2).
[23] *See id.*
[24] *See id.*

this bill to all drugs (not just those prescribed for off-label use), and requires that pharmacists generally defer to the prescriber in most, if not all, instances. Second, this requirement creates a scheme that pharmacists will not always be able to comply with. That is, because a pharmacist only has 24 hours to document their objection in the patient's medical record, the pharmacist must be able to actually make contact with the prescriber very quickly.[25] Unfortunately, there will almost certainly be instances when contact between the pharmacist and the prescriber cannot be made in the allotted time period, yet this bill fails to explain what would take place when such a situation occurs. For example, would there be an extension granted to document an objection until the pharmacist can reach the prescriber? Would the pharmacist lose the opportunity to document their objection in the medical record? Would the prescriber be subject to any sort of liability if they purposely avoided the pharmacist's attempts to make contact? In short, not only does H.B. 12 retain the requirement that pharmacists document their objections in a patient's medical record, but H.B. 12 adds a communication obligation that could potentially prevent the pharmacist from timely documenting their objections as contemplated under many circumstances, which could create potential liability for pharmacists.

2. The Lack of Clarity Regarding an Objection Based on a Moral, Ethical, or Religious Belief or Conviction

As referenced in Section III.1. above, a pharmacist, pharmacy, hospital, or inpatient facility is permitted to refuse to dispense a drug when it has a moral, ethical, or religious belief or conviction that conflicts with dispensing the drug as provided in O.R.C. § 4743.10.[26] With that being said, the proponents of H.B. 12 seem to read O.R.C. § 4743.10 in a self-serving manner and narrow the statute's applicability to the use of conscience-based objections for religious beliefs. As a result, the extent to which a pharmacist can object for moral or ethical reasons is unclear. For example, it is fair to question whether a pharmacist would be entitled to raise an objection under H.B. 12 based on moral or ethical grounds to dispensing a drug due to a lack of scientific evidence supporting the prescribing or dispensing of the drug.

Moreover, O.R.C. § 4743.10 states that it only applies to specific "health care service(s)" which include the dispensing or administering of a drug.[27] While we expect that this statute was originally enacted with the intent to allow for conscience-based objections to specific categories of medications (such as medications used to terminate pregnancy), it is important to consider whether this conscience-based objection could be broadly interpreted to apply to a wide array of drugs or medications as political views on those drugs evolve. While the sponsors of H.B. 12 would likely refute broad applicability, this is an incredibly important principle to consider should some version of H.B. 12 be enacted, as morality and ethics are not solely linked to religion or other political issues for many in the health care industry.

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[25] *See id.*
[26] *See* O.R.C. § 3792.08(C)(1)(a).
[27] *See* O.R.C. § 4743.10(A)(1).

3. The Immunity Protections Created by H.B. 12 are Underinclusive

While H.B. 12 provides a mechanism for health care professionals to obtain immunity when dispensing drugs that they have objective, good faith, and scientific objections to, this mechanism to obtain immunity remains gravely underinclusive.

For one, while pharmacists, pharmacies, hospitals, and inpatient facilities have the ability to document their scientific objections to the administration or dosage of a drug, H.B. 12 remains silent as to whether such immunity would apply to other health care professionals.[28] We interpret this silence to mean that pharmacists are the only health care professionals involved in the provision of drugs to patients who are eligible for the immunity set forth in the bill. This means that health care professionals, such as pharmacy technicians who assist with the dispensing of prescriptions, do not appear to have immunity under H.B. 12.

Second, H.B. 12 fails to make reference to any sort of immunity for criminal liability. As discussed in our comments to Sub. H.B. 73, the silence on this matter suggests that pharmacists and other health care professionals can be held criminally liable for dispensing drugs even in instances when such professionals objected, but were still forced to dispense the drugs. As such, prior to enactment of this bill, immunity should be extended to all professionals involved in the drug dispensing process, and all such professionals and other entities should be granted immunity from criminal liability for actions that they are mandated to take under H.B. 12.

Third, as noted above, because of the unworkable conflicts created by H.B. 12 as related to existing legal obligations for pharmacists as compared to the new, conflicting obligations that would be imposed here, pharmacists, other professionals in the drug dispensing process, and pharmacies should receive full immunity for a lack of compliance with those existing legal requirements trampled by H.B.12.

4. H.B. 12 Opens Retail Pharmacists up to Additional Liability

As discussed at various points throughout this memorandum, pharmacists may only obtain immunity after explaining and discussing their scientific objection with the prescriber and documenting such objection in the patient's medical record.[29] However, the reality of the situation is that pharmacists in a retail setting may not always know the diagnosis of individuals for whom drugs have been prescribed, and therefore, will not always know why a drug is being prescribed. Moreover, if a pharmacist is unaware that a drug is being prescribed for off-label use or otherwise in a clinically inappropriate manner, the pharmacist would not even know to contact the patient's prescriber to inquire further or otherwise document an objection in the medical record to gain

[28] *See* O.R.C. § 3792.08(C)(2).
[29] *See id.*

immunity. Hence, just as occurred in Sub. H.B. 73, H.B. 12 opens retail pharmacists up to liability beyond the liability that an in-house pharmacist may be subject to due to access to less information. The only alternative – the pharmacist contracting the prescriber each and every time for every drug prescribed prior to dispensing – seems overly burdensome, impractical, and could create material dispensing delays for legitimate prescriptions in an often already-stretched-thin retail pharmacy environment.

5. The Failure to Reconcile the Requirements of H.B. 12 with the Obligations of Health Care Providers to Operate Within the Standard of Care, and to Protect Patients from Harm

As referenced above and discussed in further detail below, requirements in H.B. 12 will, in some cases, conflict with the applicable standard of care for the treatment of patients.

i. The Creation of an Alternative Standard of Care

To begin, health care professionals are required to always treat their patients within the applicable standard of care. While the established standard of care may evolve over time, there are not multiple standards. Although there may be multiple treatment options within the established standard of care, there remains one singular standard.

The Ohio Supreme Court has clarified that "the standard of care applicable to medical professionals is to exercise the degree of care that a medical professional of ordinary skill, care, and diligence would exercise under similar circumstances."[30] Moreover, the State Medical Board of Ohio may discipline the holder of a physician's license for the "failure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease."[31] Likewise, similar disciplinary action can be taken against pharmacists by the Ohio Board of Pharmacy.[32]

However, H.B. 12 seeks to alter the applicable standard of care to what is referred to as an "alternative standard of care" based on a prescriber's own subjective opinion. This new standard of care almost certainly falls below the established standard in Ohio, which could pose significant dangers to patients.

Moreover, not only do we expect this alternative standard of care to be rejected by professional liability insurers, but we also expect this alternative standard to be rejected by payors who seek to deny patient claims for benefits due to lack of medical necessity, lack of FDA

[30] *Cromer v. Children's Hosp. Med. Ctr. of Akron*, 29 N.E.3d 921, 929 (Ohio 2015) (emphasis added).
[31] O.R.C. § 4731.22(B)(2).
[32] *See* O.R.C. §§ 4729.16(A)(2)(b) and (C)(6).

approval, or other similar grounds. Payors will not want to pay for initial treatments with unknown efficacy, let alone the expenses associated with potential complications arising from such experimental treatments. As a result, the alternative standard of care created in H.B. 12 creates a regime whereby patients may be left without coverage for treatment that is sanctioned by the bill, and prescribers and pharmacists may lack professional liability coverage for the actions they are permitted or often required to take under the bill.

Additionally, by altering the standard of care to effectively be whatever the prescriber thinks it should be, prescribers and pharmacists may be subject to more professional liability lawsuits while a patient's ability to succeed in such lawsuits may simultaneously be reduced. The thought here is that the alternative standard of care will encourage care and the mandatory dispensing of prescription drugs that could lead to adverse health outcomes. All the while, if the standard of care becomes the prescriber's subjective opinion demonstrated by their prescribing practices, it is unclear how a patient could ever prove that the prescriber or pharmacist fell below the applicable standard of care to recover in a professional liability action. A patient's ability to succeed upon a professional liability claim is reduced even further because the patient presumably would have provided "informed consent," which may not be all that informed due to a lack of reliable scientific research into a drug's use and potential adverse outcomes. Therefore, because of the limits on professional licensure board action discussed in Section III.7., unscrupulous practitioners could prey upon unsuspecting patients desperate for certain treatments until such time that the practitioner has acted with sufficient recklessness or gross negligence so that the professional licensure board may act.

Lastly, H.B. 12 dangerously conflates the prescribing of drugs with a health care provider's First Amendment right to the freedom of speech under the United States and Ohio Constitutions. Specifically, professional discipline, fines, and other regulatory sanctions cannot be pursued against a prescriber, pharmacist, or other licensed health care professional for publicly or privately expressing an opinion regarding the safety, risks, benefits, or efficacy of a drug or other medical intervention because that opinion does not align with the opinions of health authorities.[33] In fact, under H.B. 12, a health care professional can only be found liable for a medical act if it causes actual patient harm.[34] Beyond altering our traditional understanding of medical malpractice, making the prescribing, dispensing, and administering of drugs a "free speech issue" effectively eliminates the standard of care as we know it. As a result, so long as the prescriber's action does not cause actual patient harm, the prescriber is permitted to take the action regardless of whether it is contrary to the positions set forth by professional licensing boards, the Ohio Department of Health, or any other state agency responsible for the licensure or regulation of health care professionals. Moreover, the ability to take action apparently only kicks in once harm is actually

[33] *See* O.R.C. § 3792.08(F).
[34] *See id.*

done, which completely flies in the face of the role of federal and state regulators to promote safety and actually protect the public from harm.

ii. H.B. 12's Requirements Continue to Conflict with Pharmacists' Obligations under the Established Standard of Care

The established standard of care for treatment of various diseases and conditions often includes the off-label use of drugs. However, such use should be widely accepted by health care professionals to be within the standard of care. Moreover, pharmacists and other health care professionals go through extensive training to obtain and maintain professional licensure. That training includes a deep understanding of the importance of the scientific process, clinical interactions and outcomes, and the scientific research which should be undertaken prior to utilizing drugs for off-label use.

H.B. 12, however, contemplates *any* off-label use of drugs – not just those that are generally-accepted by the medical community. This presents a legitimate safety issue for patients and could conceivably allow prescribers to prescribe drugs that may be dangerous to patients, in any way they see fit, regardless of the lack of general acceptance by the rest of the medical community. In fact, H.B. 12 permits a prescriber to issue a prescription drug so long as the prescriber has obtained "informed consent" from the patient or the patient's representative.[35] To obtain informed consent, a prescriber simply needs a patient or their personal representative to authorize, or agree to accept, a specific drug after informing the patient of:

(1) The patient's diagnosis, if known;
(2) Information about the drug consistent with current law and practices for on-label use;
(3) Any other available information related to the risks and benefits of options pertaining to the drug's off-label uses, including the option of foregoing treatment with the drug; and
(4) Any known financial conflicts of interest the prescriber may have regarding the recommended drug.[36]

Hence, while the risks and benefits of off-label use must now only be disclosed *if/when known*, a prescriber is still permitted under H.B. 12 to suggest drugs for off-label use without providing the associated risks and benefits when such information is unavailable. As a result, some of the off-label uses permitted by the bill may not have been properly vetted or tested, and therefore, would not fall within the traditional standard of care. Put another way, H.B. 12 effectively eliminates the need for any underlying medical substantiation for prescribed medications. We likewise question how "informed" certain informed consents will ever be when associated risks and benefits information is simply not available.

[35] *See* O.R.C. § 3792.08(B).
[36] *See* O.R.C. § 3792.08(B)(1)–(4).

Furthermore, H.B. 12 has failed to add any language that would require prescribers to obtain test results or screens for a particular disease, illness, or infection prior to issuing a prescription for the patient's use. Similarly, H.B. 12 has failed to require prescribers to confirm a patient's exposure to a disease, illness, or infection prior to issuing a prescription for the patient's use. While H.B. 12 has struck the provisions that expressly exempted prescribers from obtaining any of the aforementioned test results or confirming the patient's exposure to certain illnesses, the bill's silence on the matter suggests that such tests and questions are still unnecessary to engage in when prescribing medication pursuant to H.B. 12.[37] Practically speaking, this silence means that prescribers are permitted to prescribe drugs to treat patients prior to actually diagnosing such patients. This result is blatantly in conflict with the established standard of care.

Despite the fact that an off-label use may not be safe or generally accepted by the medical community, H.B. 12 requires pharmacists to dispense off-label drugs that have been prescribed unless the pharmacists (1) have a moral, ethical, or religious objection that conflicts with dispensing the drug (the interpretation of which is unclear, as described above), or (2) are aware of some other life-threatening allergic reaction to the prescribed drug or there is a life-threatening contraindication.[38] By drastically narrowing the circumstances under which a pharmacist can refuse to dispense a prescription, H.B. 12 effectively eliminates a pharmacist's duty to consider peer-reviewed medical literature or other established industry resources prior to dispensing prescriptions.[39] Further, as discussed in Section III.1. above, even when a pharmacist has an objective, good faith scientific objection (but is still required to dispense the prescription), the pharmacist must jump through regulatory hoops required by H.B. 12 to avoid potential civil, professional, and administrative liability for doing so.[40]

Lastly, there could be many serious contraindications that do not rise to the level of being "life-threatening" for which a pharmacist should be able to decline the dispensing of a prescription. In fact, a patient may remain alive, but have a terrible quality of life due to known contraindications which do not present as life-threatening, but which could have been prevented if the pharmacist could have exercised the appropriate and necessary discretion. As such, pharmacists should have more discretion on when not to dispense due to potential contraindications, including when harm may be serious or the potential for harm is not actually known.

6. H.B. 12 Retains a Requirement Imposed Upon Pharmacists to Allow Patients to Self-Pay

Under the revised language of H.B. 12, a prescriber or pharmacist is required to notify a patient of the option to pay out-of-pocket for a drug in an outpatient pharmacy setting if the drug

[37] *See* O.R.C. § 3792.08(B); *see also* Sub. H.B. No. 73, *supra* note 2, at § (B).
[38] *See* O.R.C. § 3792.08(C)(1).
[39] *See* O.A.C. §4729:5-5-8(C). As part of a pharmacist's prospective drug utilization review, pharmacists are currently required to consider peer-reviewed medical literature prior to dispensing prescriptions.
[40] *See* O.R.C. § 3792.08(C)(2).

is not covered by a patient's health benefit plan or if the patient does not want to wait for prior authorization.[41] Furthermore, "the prescriber or pharmacist must notify the patient of the estimated out-of-pocket costs for the drug, and the pharmacist must offer the drug at an upfront, out-of-pocket cost to the patient."[42]

With that said, permitting patients to engage in upfront payments of an otherwise covered medication could violate a provider or practitioner's participating provider/network agreement with the patient's insurer or third-party administrator. Even if such a requirement does not violate network agreements, payors may enact specific exclusions around treatment pursuant to H.B. 12 such that patients will be left to pay for more drugs when they are being prescribed for off-label use. Because payors are unwilling to take on all known liabilities associated with medically appropriate treatment, it is very unlikely that payors would take on considerable unknown liabilities associated with the prescribing of off-label medication pursuant to H.B. 12.

Moreover, such a scheme may also lead to point of service issues for retail pharmacies. Specifically, patients may direct their frustration with higher prescription drug prices at the pharmacists who are helping them as opposed to the insurer or other payor who excluded the prescription from coverage under the circumstances prescribed.

Lastly, it is worth reemphasizing that the requirement to offer a self-pay option applies to all drugs, not just those prescribed for off-label use. Therefore, the issues discussed in the preceding paragraphs will apply on a far wider basis under H.B. 12 than they would have under Sub. H.B. 73.

7. The Failure to Recognize that the Proposed Bill Interferes with and Limits the Regulatory Powers of State Agencies and Health-Related Professional Licensing Boards to Discipline Health Care Entities, Prescribing Practitioners, and Pharmacists

H.B. 12 seriously limits the power of state agencies and professional licensing boards to take adverse action against health care professionals, facilities, and entities for unlawful, unethical, unauthorized, or unprofessional conduct that was taken pursuant to this bill.[43] As referenced above, state agencies and licensing boards may only take action against such professionals, facilities, and entities when their actions constitute recklessness or gross negligence.[44] As a result, this bill fails to consider the fact that each such agency and professional licensing board has already established licensure requirements and related standards of conduct for each health care entity and professional license holder being regulated. Hence, just like what would have occurred under Sub. H.B. 73,

[41] *See* O.R.C. § 3792.08(D)(1).
[42] *Id.*
[43] *See* O.R.C. § 3792.08(E).
[44] *See id.*

H.B. 12 would create substantial conflicts with existing law and would change longstanding, established standards of conduct without the input of the relevant state regulators and professional licensing boards charged with regulating the health care industry and keeping the public safe.

Furthermore, if the prescriber licensing boards are only permitted to "investigate," but cannot take any administrative or disciplinary action against licensees, then there is no real deterrent or punishment for bad actors. The leverage professional licensure boards currently possess is their broad authority to investigate and *discipline* licensees, which has the power to set in motion a host of very negative professional consequences. This disciplinary power creates accountability and effectively allows the licensing boards to cause professionals reputational harm or even to take away the professional livelihood of such licensees. By taking this leverage away from the licensing boards – especially considering how H.B. 12 seeks to change the established standard of care for prescribers – licensing board powers will be limited in a way that fundamentally contradicts with existing law and seriously endangers patients.

Lastly, because the standard of care is being altered under H.B. 12, the parameters that define "gross negligence" and "recklessness" become more ambiguous than ever before. Now that the standard of care will ostensibly be reduced to a prescriber's subjective opinion, it will be difficult to determine, for example, how many patients the prescriber will need to harm with the same drug before the prescriber's actions will constitute gross negligence or recklessness. We do not know at this time how many Ohio patients will need to be harmed before the regulatory agencies put in place to protect them can actually intervene in any meaningful way.

8. The Failure to Reconcile Certain Requirements of H.B. 12 Which Likely Violate Federal Law

Article VI of the United States Constitution clearly establishes that the U.S. Constitution, federal laws, federal regulations, and federal treaties take superiority over similar state laws.[45] Therefore, to the extent that federal law regulates the prescribing or dispensing of off-label drugs, compliance with federal law is paramount. Moreover, the Ohio Board of Pharmacy has enacted a rule requiring that "(a)ll outpatient prescriptions issued by a prescriber . . . (b)e issued in compliance with all applicable federal and Ohio laws, rules, and regulations."[46] In other words, existing Ohio law clearly recognizes that federal laws must be followed when prescribing outpatient prescriptions.

With all this in mind, H.B. 12 has omitted language found in Sub. H.B. 73 that restricted state entities' ability to enforce rules and orders issued by federal agencies when such rules or orders prohibited the prescribing or dispensing of an off-label drug. While this is certainly a step in the right direction, Supremacy Clause issues remain in H.B. 12. Specifically, H.B. 12 only

[45] *See* U.S. Const., Art. VI.
[46] O.A.C. 4729:5-5-15(B)(17).

references federal law as superseding the language in the bill when it relates to controlled substances and drugs that are subject to an FDA risk evaluation and mitigation strategy. While this may seem like deference at first, such language indicates that other federal laws that implicate the prescribing and dispensing of drugs are not superior to the similar state laws that H.B. 12 intends to create. To resolve this potential constitutional issue, the bill must be revised to clearly state that all applicable federal laws take precedence over conflicting laws created by H.B. 12.

IV. Issues Found in H.B. 12 That Relate to Hospitals and Inpatient Facilities

Although not the focus of this memorandum, we wanted to provide a brief overview of the ongoing issues that exist in H.B. 12 that relate more specifically to hospitals and inpatient facilities to demonstrate that the very serious issues presented for Ohio pharmacists and pharmacies are not even the full list of dire implications under H.B. 12. For example, such issues include:

- H.B. 12 requires hospitals and inpatient facilities to allow drugs prescribed by in-house prescribers to be brought in from outside of the inpatient setting when such drugs are not already available or in the case that the hospital or inpatient facility's staff decline to dispense such drugs. With that being said, safeguards have been proposed in H.B. 12 so that these drugs are now more safely and effectively brought into the facility.[47]

- Similar to Sub. H.B. 73, if a patient's in-house treating prescriber is not available to administer an identified drug and the medical staff at the hospital or inpatient facility who are involved in the patient's care are unwilling to administer the identified drug due to moral, ethical, or religious objections, H.B. 12 permits the patient's prescriber to designate a delegate to administer the drug. Delegation must be made pursuant to sections 4723.48, 4723.489, 4730.203, and 4731.053 of the Revised Code, and the delegate must meet the hospital or inpatient facility's guidelines and accreditation standards for drug administration.[48]

- H.B. 12 has struck the language found in Sub. H.B. 73 that would have permitted a patient's outpatient physician prescriber to apply for and obtain temporary privileges to treat a patient with drugs for off-label use at a hospital or inpatient facility.[49]

- H.B. 12 has made it difficult for practitioners to modify or discontinue an in-house prescriber's orders for a drug. As proposed in H.B. 12, modification or discontinuation of an in-house prescriber's order can only be made if: (1) the in-house prescriber is consulted and agrees to the modification or discontinuation; (2) the patient or the patient's personal representative requests in writing to discontinue the drug or consents to the modification;

[47] *See* O.R.C. § 3792.08(C)(3)(b)(i).
[48] *See* O.R.C. § 3792.08(C)(3)(b)(ii).
[49] *See* Sub. H.B. No. 73, *supra* note 2, at § (C)(4).

or (3) in an emergency when there is not time to contact the in-house prescriber for consent or it is not possible to contact the in-house prescriber, the hospital or inpatient facility shall follow the hospital or inpatient facility's existing protocol for patient care.[50] This new provision is troublesome for multiple reasons. For one, the requirement that a request for discontinuation be made in writing is overly restrictive because patients and their personal representatives may not always be able to make such requests in writing due to a variety of potential circumstances. Second, other than in the case of an emergency, this provision essentially bars the clinical staff at a hospital or inpatient facility from changing a rogue prescriber's drug order even when the clinical staff agree that the drug order is causing harm to the patient or the drug is no longer (or never was) necessary for the patient's treatment.

- A new provision has been added to H.B. 12 that would allow a patient or the patient's personal representative to decide whether to continue the use of a drug when there is a disagreement on whether to continue the drug between the patient's in-house prescriber and other medical staff at the hospital or inpatient facility who are involved in the patient's care. Such a decision cannot be made until after the patient or the patient's personal representative has discussed the risks and benefits of continuing the drug with the in-house prescriber and the other medical staff involved in the patient's care and the giving of informed consent by the patient or their representative.[51] Again, this raises the issue of informed consent and how truly "informed" it will ever be in some circumstances where the benefits and risks of a particular drug are not even fully known.

- H.B. 12 creates a mechanism that permits a patient to transfer out of a hospital or inpatient facility that does not have an in-house prescriber willing to prescribe a certain drug that the patient wishes to try to treat their condition, to a hospital or inpatient facility that is willing to accept and treat the patient with the use of said drug. Furthermore, the new provision expressly prohibits a hospital or inpatient facility from obstructing or intentionally delaying the transfer of the patient.[52] As a result of this provision, hospitals and inpatient facilities may feel pressure to begin transferring patients who, under normal circumstances, would be in too poor of a condition to be transferred, out of fear that the hospital or inpatient facility's failure to transfer the patient will be perceived as obstruction or intentional delay here. Moreover, this process assumes there is a willing provider that will accept the transfer, which there may not always be, and H.B. 12 does not address potential liability for the hospital or inpatient facility associated with the transfer.

[50] *See* O.R.C. § 3792.08(C)(4).
[51] *See* O.R.C. § 3792.08(C)(5).
[52] *See* O.R.C. § 3792.08(C)(6).

V. Conclusion

While some of the issues identified in Sub. H.B. 73 have been addressed in H.B. 12, the Right to Try Act, as currently proposed, retains many of the serious concerns we had previously identified for retail pharmacists and pharmacies and even presents a few additional areas of serious concern. In short, any potential benefit associated with H.B. 12 is greatly outweighed by the danger it presents to all Ohioans and the potential challenges and liability it presents for health care providers. Please let us know if you have any questions or wish to discuss further any of this analysis.