VORYS COMMENTS 6/5/2024

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Committees
Health, Chair
Medicaid
Insurance
Education

Stephen Huffman
5th District

To: Representative Jennifer Gross
From: Senator Stephen A. Huffman
Date: March 22nd , 2024
Re: Interested Party Meeting Follow-up

Representative Gross,

Thank you for your participation in our IP meeting on H.B. 73 as it was very informative and enlightening. I support the goal of H.B. 73 to increase access of off-label medications with ease and without punishment for the best interest of the patient. The main concerns as many stated in the IP meeting were that as currently written, there are unintended consequences. I will outline my main concerns and what others have expressed. As the sponsor, I will ask you to resolve the issues that are amendable to you by drafting changes directly with LSC. After you have the next version, we can discuss areas that have been addressed and areas where you disagree.

VORYS GLOBAL COMMENTS: Overall, there seems to be a fundamental misunderstanding of informed consent and standard of care, which flows through multiple of the responses here such that we wanted to address each of these issues more globally.

- **As written, Sub HB 73 arguably alters the existing informed consent process surrounding prescribing medications in a way that may not actually provide more protection to patients or prescribers relative to the off-label prescribing of medications. First, other than in limited circumstances, separate informed consent as contemplated here for a specific medication (beyond general informed consent for treatment) is not usually obtained by a prescriber, although documentation in the patient's medical record of the discussion surrounding any treatment, including medications, should always exist at the very least (and, more typically, the prescriber will maintain a separate informed consent for treatment document). Thus, there is arguably an additional step here. Second, while we do not necessarily object to the creation of an additional step for informed consent in this context to improve patient safety, we do question the validity of this informed consent in many instances. Informed consent involves the prescriber actually understanding the risks and benefits, adequately explaining those risks and benefits to the patient, and the patient knowingly agreeing to the off-label medication with full knowledge of the risks and benefits. Here, will a prescriber even be able to adequately notify the patient of all risks and benefits for all potential medications when prescribed off-label, given that the medication isn't being used for its studied and FDA-approved purpose such that there may be little to no scientific evidence in many instances showing the risks and benefits of a particular off-label use? If the prescriber cannot adequately inform the patient of the risks and benefits in situations where such scientific evidence does not exist, is the consent really even informed at that point? We would argue no and, at the very least, the prescriber should be required to inform the patient of additional information (e.g., that the medication is being prescribed off-label, is not FDA-approved for the prescribed purpose, and that**

the prescriber simply does not have objective scientific evidence regarding the risks and benefits and is prescribing based on the prescriber's subjective opinion). If Sub HB 73 is to be enacted in some form, we do not feel the informed consent provision goes far enough to protect patients by revealing that what is being prescribed may be, in some instances, based solely on fringe science or the prescriber's own subjective opinion, which may be motivated by religion or politics instead of science. Notably, the definition of "informed consent" also only applies to physicians, but not other potential prescribers (like physician assistants or nurse practitioners), but the broader term "prescriber" is used in other places so there is an internal inconsistency in the language used.

- **Further, the concept of "standard of care" is completely misconstrued in Sub HB 73. There is an established standard of care, which may evolve over time, but there are not multiple or alternative standards of care (although there may be multiple accepted treatment options within the established standard of care). The Ohio Supreme Court has established 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.*" *Cromer v. Children's Hosp. Med. Ctr. of Akron*, 29 N.E.3d 921, 929 (Ohio 2015) (emphasis added). Further, the State Medical Board of Ohio, for example, 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." O.R.C. §4731.22(B)(2). Likewise, similar action can be taken against pharmacists by the Ohio Board of Pharmacy. ORC §§4729.16(A)(2)(b) & (C)96). As written, Sub HB 73 seeks to alter the applicable standard of care from what is currently established under Ohio law to what is referred to as an "alternative standard of care" based on the prescriber's own subjective opinion, with little to no discretion for pharmacists. Thus, not only does this conflict with controlling authorities, as well as Medical Board, Pharmacy Board, and potentially other professional licensure authorities on standard of care, it arguably creates an entirely new standard of care which need not rise to the level of (meaning falling below) the established standard of care currently accepted in Ohio, which could pose significant danger to patients. We would expect this "altered" standard of care to not only be rejected by professional liability insurers (such that prescribers and pharmacists may be engaging in activity blessed by this bill for which they do not then have professional liability coverage), but also rejected by payors who may seek to deny claims due to lack of medical necessity, lack of FDA approval/experimental treatment, or other similar grounds, as payors would not want to pay for an initial treatment of unknown efficacy, let alone the expense of potential complications arising from such a treatment. All of this means that the patient may be left without coverage for treatment blessed by this bill, and prescribers and pharmacists may have no professional liability coverage for conduct blessed by this bill. Importantly, however, altering the standard of care to be, effectively, whatever the prescriber thinks it should be would also seem to largely negate all patient claims for professional liability – if the standard of care is now the prescriber's subjective opinion, which is demonstrated by the prescriber's prescribing practices, how would a patient ever be able to show that the prescriber or pharmacist fell below the applicable standard of care and recover in a legitimate professional liability action (for which the prescriber or pharmacist may not have professional liability coverage anyway), especially when the patient will have presumably signed some "informed consent" which itself may not have been informed at all. Because of the limits on licensure board action absent "recklessness or gross negligence," uninformed or unscrupulous practitioners could prey on unsuspecting patients desperate for some treatment until such time as sufficient harm has been done that the licensure board may act.**

- **Note that most of the comments initially made and the related responses are tied to prescribers as opposed to pharmacists. Our comments are generally tailored accordingly. That said, however, flowing through the entirety of this bill is the attempt to significantly curtail a pharmacist's professional discretion granted under the law currently, thereby forcing a pharmacist to dispense off-label medications, even in the face of an objective, good faith, scientific objection, which is dangerous for both the patient and the pharmacist in terms of maintaining adequate professional liability coverage and licensure implications, particularly given the conflicts between this bill and**

current law governing the practice of pharmacy in Ohio.

1. As currently written, H.B. 73 could result in a vast expansion of abortion in the state of Ohio.
   1) The recent passage of The Right to Reproductive Freedom with Protections for Health and Safety has created an environment that negates any possible impact of House Bill 73. Sadly, abortion pills can be ordered by mail without even having a prescription. HB 73 cannot "expand" on the level of abortion access already in existence here in Ohio. In addition, we amended your section of concern regarding "no required testing" before prescribing. The wording was changed to ONLY apply to "diseases and illness". Pregnancy is not a disease or illness, so nothing in the amended version prohibits pregnancy testing. You mentioned that Accutane was a concern, but that drug is listed as a REMS drug which is clearly addressed in the (-6) version of HB 73 (Lines 87-91). Take note, both the current and House passed versions of HB 73 re-enforce that moral and religious exemptions for prescription filling are still available. Any pharmacist may use this exemption if there is a moral concern that the drug prescribed will be used for the purpose of abortion.

VORYS COMMENTS:

- **The statement that abortion pills can be ordered online without a prescription is simply incorrect. Mifepristone and misoprostol both require a prescription. This statement may be an attempt to mischaracterize emergency contraception, like Plan B and similar medications, which prevent (not end) pregnancy. Nothing in the related amendment to the Ohio Constitution or otherwise in Ohio law supports this statement.**

- **As written, Sub HB 73 could potentially allow greater access to late-term medication abortions. For example, a medication other than mifepristone and misoprostol (such as certain cancer drugs or antibiotics) could be prescribed for an FDA-approved purpose, the patient could be informed of the risks and benefits (one of which is potentially terminating pregnancy), and the patient could execute the informed consent choosing to take the medication anyway to end the pregnancy. The same could be true for medications prescribed for off-label use which also have this potential result. Even mifepristone and misoprostol have (and are being investigated for) uses other than terminating pregnancy, such as certain gynecologic conditions, cancer, gastric ulcers, and Cushing's disease. There is also no express requirement in Sub HB 73 that a prescriber perform a pregnancy test prior to prescribing a medication that may cause pregnancy termination so a prescriber may not even know that a patient is pregnant if the patient says she is not or otherwise declines a test. When the prescriber does know, the Ohio Constitution defers to the professional judgment of a pregnant patient's treating physician in protecting the pregnant patient's life and health (presumably including mental health), even after fetal viability. Notably, a pharmacist would not even necessarily know the real reason for a prescription to be prescribed, which would undercut the pharmacist's ability to levy even a conscience-based objection to dispensing.**

- **As to medications, like Accutane, with a REMS protocol, we cannot state whether following that REMS protocol in the case of off-label use would be sufficient to address risks associated with the off-label use since the REMS protocols are designed to address specific risks associated with FDA-approved uses. It seems at least possible that existing REMS protocols may be insufficient for this purpose, but dispensing could still be possible where the prescriber confirms that the relevant REMS protocol has been followed.**

2. H.B. 73 could result in legalization of physician-assisted suicide in the state of Ohio.

2.) Euthanasia, mercy killing, or assisted suicide is not authorized by Ohio law. Death of any patient resulting from withholding life-sustaining treatment does not constitute suicide, murder or any homicide offense for any purpose. As articulated in Chapter 2133 | Modified Uniform Rights of the Terminally Ill Act; DNR Identification and Do-not-resuscitate Orders in regard to passive euthanasia: (withholding a medical intervention in order to expedite the death of the patient) Passing of House Bill 73 actually gives more rights to patients and protects the sanctity of their lives by ensuring that they are not "denied sufficient means of fluid or nutrition."

In regard to active euthanasia: (administering a medical intervention with the intent of expediting the demise of a patient) Informed consent, as now defined by the amended version of HB 73 further requires that the Physician shall provide "the nature and purpose of the recommended drug, treatment, or intervention; the burdens, risks, and expected benefits of all drugs, treatment, or intervention options, including the option of forgoing treatment; and any conflicts of interest the physician may have regarding the recommended drug, treatment, or intervention" (Line 29-30) In order to obtain this level of informed consent, a Physician must disclose that the purpose of the intervention would be to hasten the death of the individual. This act of active euthanasia does not qualify for the legal protection afforded by HB 73. Such actions are excluded, "except in cases of reckless or gross negligence" (Lines 227-228).

In summary, House Bill 73 offers additional protection against passive euthanasia and offers no protection for active euthanasia.

VORYS COMMENTS: While Ohio law does not condone mercy killing, assisted suicide, or euthanasia, and such acts are against public policy, there is the potential for medications used off-label, which carry the potential to cause death, to be prescribed for a permissible use when the patient understands that death is possible and otherwise provides informed consent (we also expect prescribers of off-label drugs to describe potential risks of off-label use broadly since such risks may not be fully known such that death may always be listed as a potential risk). Put another way, because Sub HB 73 broadly permits off-label prescribing based, effectively, on a prescriber's subjective opinion and not the established standard of care, a medication would not have to be prescribed for death, but death could simply be an accepted risk for the patient. Moreover, the prescriber may not even know of the patient's desire to end his/her own life when prescribing. As noted above, pharmacists may not have sufficient information to even object prior to being required to dispense. While these situations may be rare, they could certainly occur, along with instances where a prescriber euthanizes his own patient purposefully. While discipline or liability for the prescriber (or pharmacist, if applicable) may be possible in some instances when conduct is severe enough, the fact is that the patient at issue is still dead and cannot be brought back.

3. In its current form, H.B. 73 also allows the use of narcotics and controlled substances to be used off-label for any purpose. This would exempt health care professionals from Ohio's drug trafficking laws.

2) Narcotics are now clearly EXCLUDED in the -6 amended version of HB 73. Furthermore, the entire opioid class of medications has a post market Risk Evaluation and Mitigation Strategies (REMS). House Bill 73, as amended, also specifically now states that the off use of any medication must follow REMS requirements the same as if the medication was being used as indicated. (Lines 87-91)

VORYS COMMENTS: Narcotics/controlled substances are excluded from Sub HB 73. However, REMS protocols established to address risks associated with FDA-approved uses may not be sufficient to mitigate risk in the off-label use context, as noted above.

4. H.B. 73 would eliminate the requirement for healthcare providers to practice the minimal standard of care. Would you consider a consent form that the patient, medical provider, pharmacist and hospital all sign before the drug is received acknowledging that it is below the prevailing standard of care and current accepted medical literature? The patient would then accept all understanding and responsibility of any harm or death.

   4) We object to the idea that HB 73 would somehow "eliminate" the "minimal standard of care". Permitting an alternative standard of care does not equate to the practice of substandard care. The only deviation that you may perceive to not be "standard of care" is that there is not a requirement to have a positive test for a disease or illness performed prior to the administration of a medical intervention. This is already demonstrated in current practice with the lack of testing prior to the prophylaxis of a disease, or the treatment of individuals exposed to a disease. For example, a person is not required to test positive for influenza prior to receiving the flu shot. The second Rh-negative child born to a Rh-positive mother is not required to show signs of fetal distress before the administration of RhoGAM. Antibiotics are also commonly administered prophylactically in situations where a resulting infection is possible or likely.

VORYS COMMENTS:

- **We object to the idea that Sub HB 73 supports a prescriber's responsibility to follow the established standard of care. The above comment mentions an "alternative standard of care." As noted in our global comments above, there really is no such concept under Ohio law. The standard of care is established under Ohio law and, by definition, a level of care generally accepted by the relevant medical community. The standard of care is not what a prescriber subjectively thinks it is or should be and can get a patient to agree to, which could absolutely fall below the established standard of care.**

- **As to the flu shot and RhoGAM examples, it is true that certain preventive measures may be prescribed without further testing based on the specific history of the patient, known and preventable treatment outcomes, or the like. That said, the extent of off-label prescribing blessed by Sub HB 73 goes well beyond these limited preventive measures, which are generally accepted within the medical community and have been assessed by the medical community to present materially greater benefits than risks to the vast majority of patients. In contrast, Sub HB 73 effectively eliminates the need for any underlying medical substantiation for prescribed medications, whether for prevention or treatment, meaning the prescriber need not substantiate the need for treatment at all before prescribing an off-label medication.**

5. There needs to be a clarification that off-label drugs in this bill only apply to drugs approved by the FDA for human use, medications only approved for animal use need to be excluded.

   5) House Bill 73 as passed by the House already stated that an intervention must be legal in the state of Ohio (Line 47). Administering veterinarian medication by physicians to humans is not legal in Ohio so it does not need to be a provision in this bill. Furthermore, hospitals and physicians administered mRNA based, and other emergency use drugs that were not approved by the FDA for human use. This was not only accepted as "standard of care", but these drugs were also completely shielded from liability as were the hospitals and

providers who administered them. If this was a significant concern, where was the pushback with those interventions?

VORYS COMMENTS: There was no pushback because the mRNA vaccines were, in fact, approved by the FDA for human use utilizing the FDA's established Emergency Use Authorization process. For example, the EUAs for the Pfizer-BioNTech and Moderna Covid-19 vaccines are as follows: Pfizer-BioNTech Covid-19 Vaccine Letter of Authorization, U.S. Food & Drug Administration (May 10, 2021); Moderna Covid-19 Vaccine (2023-2024) Letter of Authorization, U.S. Food & Drug Administration (Sep. 11, 2023). Thus, use of these vaccines, based on the EUAs, was not a deviation from the established standard of care and did not create an alternative standard of care.

6. H.B. 73 grants immunity to the provider, but it neglects to grant immunity to the hospital, pharmacist, and other health care providers in and out of the hospital.

   6.) The House passed version HB 73 already included immunity for hospital pharmacists Section C (2) and the -6 version has now expanded immunity for other hospital health providers when an outside physician is providing care under "temporary privileges"(Lines 196-201).

VORYS COMMENTS: To the extent there would ever be a scenario in the hospital/inpatient facility context where an outpatient prescription may be filled by a retail pharmacist (or a pharmacist other than an in-house hospital or facility pharmacist) and then brought to the patient on-site, the broadest possible immunity should be extended to those retail and other non-hospital/facility pharmacists as well when they are required to dispense to an inpatient. As written, Sub HB 73 only grants immunity to retail pharmacists when they also document an objective, good faith, and scientific objection. Further, the immunity granted is only for civil and administrative liability, not immunity for potential criminal liability or other serious consequences that may arise under federal law, as further discussed below.

7. HB.73 needs to directly address the issue and define when a pharmacist has an, "objective, good faith and scientific objection to the administration or dosage of the drug for that patient." This appears to say that a pharmacist does not have to distribute a drug if it does not meet the minimal standard of care which is the same as a scientific objection.

   7.) The documentation of a "good faith objection" is the requirement to have liability protection secured for the pharmacist in both the inpatient and outpatient setting. The liability protection is only given "when a pharmacist must dispense" when they object but do not have a moral objection or a "life threatening" contraindication that allows them to NOT have to fill the drug prescribed (Lines 97-104). "Except for either" of those 2 reasons (Line 96) "a pharmacist shall dispense, and a hospital or inpatient facility shall allow the dispensing of..."(Line 92).

VORYS COMMENTS: As written, Sub HB 73 only allows a pharmacist to decline to dispense based on moral/religious objections, not scientific objections, or when there are "life-threatening" contraindications.

- **As to contraindications, it would seem there could be many serious ones that may not rise to the level of being life-threatening for which a pharmacist should be able to decline dispensing an off-label medication, especially in this context when there may be a lack of knowledge in the medical community regarding contraindications and potential adverse outcomes (which then ties back to the issues with informed consent). 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 appropriate and necessary discretion, especially when considering that the pharmacist may have more complete or better information than an off-label prescriber regarding the array of medications being taken by a specific patient (particularly,**

where there are multiple prescribers involved). 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.

- **Proponents of Sub HB 73 seem to read ORC §4743.10 in a very self-serving manner and really only in the religious context, but it actually protects objections based on conscience in the moral and ethical contexts as well, which it would seem need not be based in religion. How would Sub HB 73 treat a pharmacist's moral or ethical objection to dispensing an off-label medication due to lack of scientific evidence supporting the prescribing or dispensing or other scientific evidence presenting contraindications? If based on a pharmacist's moral or ethical beliefs, or the ethical pillars of the profession, refusing to dispense should be permitted. ORC §4743.10 says that it only applies to a specific "health care service," including dispensing or administering a medication. While we expect this was intended to allow for conscience-based objections to a specific category of medications (like medication used to terminate pregnancy), consideration should be given as to how broadly this exception can be interpreted or extended here if some version of Sub HB 73 is to be enacted.**

8. All conflicts with federal law and the DEA for pharmacists need to be resolved in some way. Particularly, it needs to be addressed as it pertains to narcotics, drug trafficking, and controlled substances. This needs to include the federal laws concerning medication reconciliation requirements.
   8.) Again, narcotics are clearly excluded in the current HB 73 -6 version. There is nothing in House Bill 73 that inhibits, prevents, or encumbers drug reconciliation. REMS drugs were also addressed in the (-6) version as mentioned in concern #3.

VORYS COMMENTS: Narcotics/controlled substances are excluded from Sub HB 73. Please advise if there are specific remaining concerns.

9. There needs to be a mechanism to track the use of off-label prescribing that is below the standard of care prescribing. Currently, H.B. 73 removes the ability of the State Pharmacy Board and the State Medical Board to take any investigative or disciplinary action for adverse outcomes. What can they do when a drug is prescribed ten times and each time the patient dies, should the State Pharmacy Board and State Medical Board continue to allow this to happen? What is the morbidity and mo1iality rate acceptable before the state can take action?
   9.) Each hospital already has a mechanism of tracking every medication and dosage given to the patient including any off-label use drugs or home medications.
   The assertion that a doctor prescribes a drug 10 times and each time the person dies is outlandish. A doctor that continues to kill patients with the same drug would constitute "gross negligence", which is clearly stated in both the previous and current -6 version of the bill. Nothing in this legislation says that the Pharmacy board or medical board cannot "investigate" a doctor. It only states they cannot take "administrative or disciplinary action" against their license unless they are found to be grossly negligent. HB 73 (-6 version) states that "health related licensing" boards "shall not pursue an administrative or disciplinary action against the prescriber, pharmacist, hospital, or facility, except in cases of recklessness or gross negligence" (Lines 225-228). In addition, prescribers are not immune from liability from their patients. Doctors are not any more likely to risk being sued by a patient under this legislation than they would be without this legislation.

VORYS COMMENTS:

- **Retail pharmacies may or may not have a complete picture of all off-label prescribing for a given patient, which would depend on how many prescribers and how many pharmacies a patient uses. A more comprehensive database of such information is only maintained for controlled substances in Ohio.**

- **If the prescriber licensing boards can only "investigate," but cannot take any administrative or disciplinary action, then there is no real deterrent or punishment for bad actors. The leverage professional licensure boards have currently is their broad authority to investigate and discipline licensees – e.g., to effectively take away their professional livelihood and cause reputational harm. Taking that leverage away in this context, especially when Sub HB 73 seeks to change the established standard of care for prescribers and does not further define what constitutes "recklessness or gross negligence," seems to limit licensure board powers in a way that not only contradicts existing law, but could seriously endanger patients. Licensure boards play a critical role in monitoring health care practitioner behavior and protecting the public.**

- **This response also states, in part, that "a doctor that *continues* to kill patients with the same drug would constitute "gross negligence" (emphasis added). How many patients would have to die before we have moved away from the fictional "alternative standard of care" to "recklessness or gross negligence" for which action could be taken?**

- **Prescribers and pharmacists may be subject to more professional liability lawsuits after Sub HB 73 because Sub HB 73 effectively says that the standard of care would be what a specific prescriber thinks it is or should be and can get a patient to agree to, thereby encouraging and facilitating care (and requiring pharmacy dispensing) that does not fit within the established standard of care under Ohio law, which could potentially lead to more adverse health outcomes. Again, however, we question the validity of at least some informed consent obtained in this context, which may not provide protection for prescribers ultimately depending on the circumstances. We also question whether prescribers and pharmacists would even have professional liability coverage to defend against or compensate for certain prescribing and dispensing practices blessed and required under Sub HB 73. We further question if/when a patient can even recover given Sub HB 73's change from the established standard of care to the prescriber's subjective opinion.**

10. H.B. 73 needs to address what the State Pharmacy Board should do when a drug is prescribed for an off-label use that does not meet the standard of care during a drug shortage. When a drug is prescribed in this way, it may jeopardize many more lives by creating critical shortages that deny these patients a life-saving drug.
    10.) Why would the Pharmacy Board need to take any action when there is a drug shortage when there is already a mechanism in place for drug shortages? All healthcare providers are currently notified by hospitals and pharmaceutical manufacturers when a drug shortage is experienced. At that point healthcare providers use their best clinical judgment on how to triage recourses. If an individual pharmacist feels a moral imperative not to dispense a scarce medication, then he/she can evoke the protection of moral objection to fill under section 4743.10

VORYS COMMENTS: It seems that off-label use of medications could certainly increase after Sub HB 73, which could then lead to more or different shortages than the pharmaceutical industry is accustomed to managing currently.

11. H.B. 73 needs to define, "good faith effort to acquire a drug." The meaning of this can be different depending on the patient and hospital. Is this within the county, the state, within the US, or anywhere in the world? A hospital could be taken to court if the only way to obtain a drug is from India and a patient believes that this would be a good faith effort.

    11.) A "good faith effort" holds the same definition as already stated in the Ohio revised code... a good faith effort is described as "what a reasonable person would determine is a diligent and honest effort under the same set of facts or circumstances." In addition, the version we amended for the Senate now clearly states "from another hospital or inpatient facility, or another United States distributor." (Lines 127-128)

VORYS COMMENTS: The abovementioned definition is not found in the Ohio Revised Code. We need the specific cite to understand what is being referenced. We suspect this definition may arise from a line of cases in Indiana that specifically defines good faith effort as "what a reasonable person would determine is a diligent and honest effort under the same set of facts or circumstances." *See e.g., Hamlin v. Steward*, 622 N.E.2d 535, 540 (Ind. App. 1993); *see also AquaSource, Inc. v. Wind Dance Farm, Inc.*, 833 N.E.2d 535, 539 (Ind. App. 2005); *see also Troutt v. City of Lawrence*, 2008 U.S. Dist. LEXIS 61641, *48 (S.D. Ind. Aug. 8, 2008). In each of these cases, "good faith effort" is being explained in the context of an implied contractual term under Indiana law, which is very different from our context here. As stated, in the absence of a clear definition, there could be unnecessary ambiguity on this issue.

12. Bringing in a medical provider that does not have privileges into a hospital is a concern. I believe that the medical provider should have an active license in the state of Ohio, not under investigation or pending actions from the State Medical Board, and not under investigation for fraudulent research practices.

    12.) Every Ohio medical institution has a process to vet Physicians prior to granting them privileges at their perspective institution. This vetting process is unique to each institution and should not be altered by inserting new requirements under HB 73. We feel it an overreach for this legislation to dictate each institutions vetting process for granting privileges. During the vetting process, it is typically required that an applicant have an active medical license in Ohio. Under House Bill 73, a Physician can have their application denied for cause. You alluded in concern 10 that a "drug shortage" could deny "these patients a life-saving drug", we feel it equally dangerous to deny a patient access to a Physician willing to administer a life-saving drug. House Bill 73 does NOT alter the process of credentialing Physicians, it only expedites the process.

VORYS COMMENTS: What happens if a hospital cannot meet the five-day deadline for assessing temporary privileges, particularly under the circumstances presented here when the entire purpose of the requested privileges is to initiate treatment that in-house practitioners have refused to do? Hospitals should be trusted to use their own credentialing processes and procedures, including their own timeline. Moreover, if a hospital deviates from their established credentialing process (e.g., expedites it), grants privileges under Sub HB 73, and there is an adverse patient event, the hospital could open itself up to liability or other regulatory consequences from federal regulators (CMS, The Joint Commission, etc.), other applicants for credentialing, or the patient/patient's family that is the subject of the adverse event. While Sub HB 73 purports to offer broad immunity, it cannot prevent action at the federal level – for example, hospital exclusion from Medicare (or Medicaid, which is a federal and state program), hospital loss of accreditation necessary to participate in Medicare, or the like. Similarly, if hospital privileges are denied due to competency concerns, that event would be reportable to the National Practitioner Data Bank (NPDB), which would then involve relevant state authorities, so any provisions indicating otherwise arguably conflict with

federal law.

13. Off-label prescribing that is below the standard of care should be limited to physicians and no mid-level provider or any other medical provider.

    13.) No medical provider at any "level" should be giving substandard care. Expanding treatment options to providers does not make them more likely to prescribe irresponsibly. If an Ohio patient chooses a "mid-level" provider that should not dictate whether that provider is able to give the best possible care they see fit for their consenting patient. Every Ohioan deserves to receive food, fluids, and access to the medications that can help them. One could easily argue that if the hospital "standard of care" implemented during COVID had been sufficient, then Ohio hospitals would not have ranked 35th for Covid-19 Mortality by State, then many Ohioans like Dave and Angie might still be with us, and this bill would never have been written. "Standard of Care" would be best determined by the doctor who knows their patient and has the fully informed consent of that patient or their guardian to receive that care. Please also note that outside prescribers seeking inpatient "temporary privileges" only refers to "physicians". (Lines 151-157)

VORYS COMMENTS: This statement essentially confirms that Sub HB 73 seeks to introduce a new standard of care in conflict with existing Ohio authorities, which is highly problematic, as explained above. The standard of care cannot be a single physician's or other prescriber's opinion. Further, there is a big difference between scientifically backed and generally accepted off-label use and the use of a medication, off-label or otherwise, that falls below the standard of care. While not all off-label use may fall below the standard of care, some certainly could (and licensing boards are blocked from taking any action other than investigation until the conduct is deemed to rise to the level of "recklessness or gross negligence," which is also highly problematic as explained above).

14. In a hospital setting when there is a drug used for off-label below the standard of care, there needs to be a consultation between at least the prescribing physician, patient (or durable power of health care), pharmacist, Chief Medical Officer (or their designate), Chief of Staff, and Department Head to discuss the risks, benefits, and alternatives of the drug. At an outpatient level, a physician, patient (or durable power of health care), and pharmacist (maybe others) should have a consultation.

    14) The repeated use of the term "below the standard of care" is not reflective of the reality of a doctor trying to provide his/her patient with an alternative treatment pathway. This issue was clearly addressed in the house passed version and is still present in the amended version. Lines 157-162 clearly state "then the patient's outpatient physician prescriber, after a prompt consultation with the patient's hospital or inpatient facility care team and a review of all of the patient's drugs, shall be allowed to immediately begin applying for temporary privileges with oversight, based on criteria within the hospital or inpatient facility.."

VORYS COMMENTS: As stated above, there is a definition of standard of care in Ohio, and Sub HB 73 is not consistent with it. On this specific issue, what is the consult intended to achieve if the outside physician, if granted privileges, can do whatever he/she wants, even over the objection of the other members of the hospital's or facility's patient care team's objections? If this is the case, why would a hospital ever grant the outside physician privileges in the face of such significant disagreement on care? While it is possible for a consult to potentially convince an outside physician that otherwise planned treatment is not advisable and falls below the standard of care if that is the case, it's also possible that the outside physician chooses to engage in that treatment anyway, believing that Sub HB 73 gives that physician the discretion to determine the applicable standard of care. Sub HB 73 does not require ongoing consultation with the patient's care team, nor does it address what happens in the case of a disagreement between the care team and the patient's outside physician, which seems more likely to occur if Sub HB 73 is enacted.

15. Initiating temporary changes in five days is reasonable, but a hospital must be able to abide by their current bylaws or risk being sanctioned by CMS. The providers also need to know that the results may mean that the physician is reported to the National Practitioner Data Bank, the Department of Health, or other authority as required by State and Federal law. If a hospital does not have a mechanism of temporary or emergency privileges, then H.B. 73 needs to directly address how a hospital will address this.

    15) We removed the provision for hospitals to report when a doctor applies for temporary credentials and is not approved. This was replaced with a physician self-reporting "complaint" option in instances where they feel their denial was wrongful. These complaints are saved for 7 years and are able to be public records requested to determine whether certain hospitals deny credentials based solely on the drug the doctor wants to treat with. This change was clearly defined in the LSC comp document that was sent with the newly amended bill version.

VORYS COMMENTS: As stated above, privileges that are denied by a hospital due to competency concerns will be reported to the NPDB. Any provisions in the bill indicating otherwise arguably conflict with federal law. See also comments to Q12, above.

16. Bringing in outside medications by the patient or physician also needs to be better defined. Many hospitals already have a mechanism to do this, and H.B. 73 needs to state if the hospital needs to follow them or what mechanism they need to follow to verify the strength, sterility, and ability to confirm what the drug actually is.

    17.) Pharmacists in hospitals already identify medications routinely. Every pill or capsule has a unique combination of color, size, shape, and markings. There is no need to micromanage hospital protocols for identification that are already in place. This was clearly defined in the House passed version and the current version is even clearer.

VORYS COMMENTS: It's interesting that, here, Sub HB 73 does not need to "micromanage" hospitals, but deference is not given to hospitals or other inpatient facilities – or pharmacists or pharmacies – on other aspects of this bill. Further, compounded medications in particular cannot necessarily be readily identified in the way described. We see no harm in further clarifying this issue or otherwise stating that complete discretion is given to the hospital or inpatient facility to follow their own established pharmacy processes, including the exclusion of medications that cannot be readily identified or otherwise identified as medically appropriate for the patient.

18. H.B. 73 states that the patient must first pay for the cost of the drug at a reasonable cost. The patient also should also agree in writing to pay for the increased cost of any adverse reaction or increased length of stay. Medicaid, private insurance, or the hospital should not accrue these additional costs because a patient and physician wants to take or prescribe a medication for off-label use that is below the standard of care. This should also apply for when a patient takes a medication off-label as an outpatient that causes an inpatient admission.

    18) Does this practice currently exist anywhere in medicine? The patient or their legal representative, who has given informed consent, understands that there are risks in the imperfect practice of medicine. The term "practice of medicine" represents that healthcare providers blend art and science to treat a varied array of individuals and conditions. Adding the language you're suggesting would expand the scope of House Bill 73 to set a dangerous precedence. If a patient consents to a newly FDA approved cancer treatment protocol, are they responsible to pay for any resulting side effects that lead to a hospitalization? Were the hospitals responsible to pay for renal failure treatments and dialysis that was

required as a result of the "standard of care" protocol administration of Remdisvir, or did that fall on the patient and their insurance company? How about hospital acquired secondary infections? Do hospitals cover the costs of the treatment and interventions required for patients who develop hospital acquired MRSA or bacterial pneumonia resulting from ventilation?

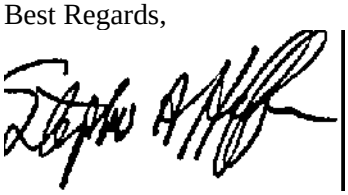
Be careful not to ask HB 73 to set a liability standard for patients and doctors choosing an alternative use for an FDA approved drug, that would not also apply to those who benefit financially from current "standard of care" protocols that could also cause harm.

VORYS COMMENTS: Public and private payors never intend to pay for all medical or prescription drug treatment that a patient may ever need or want, which is why medical/Rx plans contain important exclusions from coverage (such as "never events," which are medical errors that should never occur and are not covered), as well as cost-sharing provisions. Here, requiring upfront payment of an otherwise covered medication could violate a provider's or practitioner's participating provider/network agreement with a specific insurer or third-party administrator. The more likely scenario, however, is that payors will simply enact specific exclusions around treatment pursuant to Sub HB 73 such that the patient will be left to pay for it all, including initial treatment and potentially expensive complications down the road. That said, there is also the potential to materially increase provider charity care if the patient cannot or simply does not ultimately pay for the care provided, and the provision of some care to such a patient may be required in some instances (such as under the federal law, EMTALA, if the patient presents in a hospital emergency room). This is all foreseeable, as payors will not take on all known liabilities associated with medically appropriate treatment. Why would they take on considerable unknown liabilities associated with broad off-label medication prescribing blessed by Sub HB 73? Additional issues may also be presented with retail pharmacy point of service claims, when the patient goes to pick up their off-label prescription only to find they have no coverage and need to pay more than expected to obtain the medication – often such situations are taken out on the pharmacist when the issue is really the patient's coverage and the medication prescribed.

Thank you for your consideration on this matter, and I look forward to continued discussion on this piece of legislation.

In summary, the Sub-bill for HB 73 (-6) encompasses all the reasonable concerns included in your letter. The additional requests suggested would significantly alter the bill and create loopholes that would lead to a complete compromise of the intent of the bill and leave Doctors and their patients at the mercy of hospital board protocols and pharmacists dictating what treatments patients can receive from their provider. We hope it would not be further requested to alter HB 73 into something that would undermine the truly protective language we have diligently worked to create. My office collaborated with Ohio doctors, pharmacists, lawyers, patients and OAMF on this bill. The Dave & Angie Patient & Health Provider Protection Act is truly the "people's" legislation.

Best Regards,



Stephen A. Huffman State Senator 5th Dis