To: The Honorable Stephen A. Huffman, Chairman, Ohio Senate Health Committee

From: Ohio Pharmacists Association, Ohio Hospital Association and Ohio Children's Hospital Association

Re: Interested Party Meeting Follow-up

Chairman Huffman:

Ohio Pharmacists Association (OPA), Ohio Hospital Association (OHA) and Ohio Children's Hospital Association (OCHA) continue to have very real concerns with House Bill 73 and the negative impacts its passage would have on the health and safety of Ohioans.

We recognize and appreciate the bill sponsors' worthy intention to increase access to off-label medications in response to the very difficult circumstances many Ohioans faced during the COVID-19 pandemic. However, we believe the broad and far-reaching provisions of Substitute House Bill 73 must be addressed.

To that end, on behalf of our respective associations, we feel compelled to challenge some of the assertions being made (noted below in red) surrounding the implementation of this legislation.

We appreciate your consideration of our feedback and look forward to continuing a productive dialogue.

NARCOTICS EXCLUSION AND REMS REQUIREMENT

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)

As a point of clarification, REMS are only globally required for outpatient use of opioid analgesics, not inpatient, hospital-based usage. REMS programs are also highly variable for who is responsible – sometimes it's the physician, but often it's the organization/pharmacy managing a required program.

Pharmacists appreciate the removal of the forced dispensing of controlled substances from the bill. However, this exclusion also presents a paradox for pharmacists and prescribers. As the intent of the legislation is to unencumber prescriptive authority for off-label drug usage, making a class of drugs illegal for off-label use could be of concern for prescribers. This change limits a prescriber's off-label ability, should House Bill 73 become law. For pharmacists, we encounter daily dispensing of controlled substances, such as those indicated for anxiety, being used for sleep. This is an off-label use. Today, this occurs without incident. Under House Bill 73, it would

be illegal. For example, it is unclear if patients using Ativan (lorazepam) for sleep would still be able to obtain this medication under House Bill 73 as controlled substances would be banned from off-label use.

MINIMAL STANDARD OF CARE VS. ALTERNATIVE STANDARD OF CARE

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 sub¬standard 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.

There is no such thing as an "alternative standard of care." Period. The standard of care is the standard of care. If every physician or prescriber could define their own "alternative standard of care," then there would never be a finding of medical negligence against any medical professional because all of them would simply meet their own "alternative standard of care."

As the Ohio Supreme Court has stated for decades: "The standard of care required of a medical doctor is dictated by the custom of the profession: "In order to establish medical malpractice, it must be shown by a preponderance of evidence that the injury complained of was caused by the doing of some particular thing or things that a physician or surgeon of ordinary skill, care and diligence would not have done under like or similar conditions or circumstances, or by the failure or omission to do some particular thing or things that such a physician or surgeon would have done under like or similar conditions and circumstances * * *." Michalek v. The Ohio State University Wexner Medical Center, 2022-Ohio-3378 (citing Littleton v. Good Samaritan Hosp. & Health Ctr., 39 Ohio St.3d 86, 93, 529 N.E.2d 449 (1988), quoting Bruni v. Tatsumi, 46 Ohio St. 2d 127, 346 N.E.2d 673 (1976), paragraph one of the syllabus."

Finally, there is a distinct difference between the examples given where testing may not be necessary prior to prescription, and other equally likely scenarios where testing should be required prior to prescribing. There is a specific reference to certain vaccines or antibiotics as given without testing, and that may be appropriate (and meet the standard of care) in many cases. But there are numerous other instances where prescribing drugs without doing appropriate tests would not meet the standard of care. A physician would not prescribe a cancer drug (whether off-label or indicated) to a patient without testing the patient for cancer – doing so would not meet the standard of care. In short, in most situations testing would be required prior to prescribing a drug in order to meet the standard of care. HB 73 does not require testing in any cases involving off-label prescribing. That is dangerous and a clear departure from the standard of care in a wide variety of situations.

Another specific example: Antimicrobial stewardship programs are required by CMS Conditions of Participation. Under these programs, prescribing of antibiotics is recommended to be restricted to a limited number of physicians (providers) and/or use indications to prevent development of antimicrobial resistance. With increasing antimicrobial resistance and per CMS requirements, limitations are expected and required. This is another example of also needing to use nationally recognized guidelines to optimally use antimicrobials.

FDA Approved Drugs for Human Use

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?

We need to ensure only medications authorized or approved by the FDA for use in humans should be included.

Outpatient pharmacies are licensed to dispense medications approved by the FDA for human use. For example, we are unaware of a situation where ivermectin paste for equine use was prescribed, labeled and dispensed by an Ohio pharmacy. It is hard to imagine what possible solutions a future pandemic may hold. It is beyond difficult to respond to a circumstance that is impossible to envision today within the context of House Bill 73.

Hospital, Pharmacist and other Health Care Provider Immunity

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).

Only the hospital and pharmacist receive any liability protection. However, there are other clinicians who would be involved in the mandatory dispensing and administration of drugs (such as nurses, pharmacy technicians, and others) who do not receive any protection. In addition, if a pharmacist, hospital, or other provider is forced to dispense and administer a drug that it has a clear scientific objection to because it knows dispensing would violate the standard of care, they should be immune from suit altogether, not just immune from liability – the patient should not even be able to bring a lawsuit. However, again, granting liability protection in exchange for requiring the pharmacist or hospital to dispense a drug that the pharmacist/hospital believes will harm a patient is hardly a tradeoff that hospitals and pharmacists would welcome.

It is certainly a perverse medical and legal position to take: "I believe, based on science and my years of training and experience, this drug is likely to harm you, but the law requires me to give

it to you, but at least I know I won't be liable when this drug does harm you because the law also says I am protected from paying you any damages when you sue me for harming you, even though I was pretty sure this drug would harm you."

The processes outlined in this bill do not reflect care occurring in a hospital. The primary service/provider will take consultations or guidance from other specialties within the hospital, second opinions from outside experts, and the primary care providers at times. However, the primary admitting team is fully responsible for approving all therapies and the corresponding management. It is inappropriate for the physician's license and other health care professional's licenses to be at risk for managing the outcomes of the medications. Essentially, a physician could start a medication independently, but rely on all other management of the patient – including risks and negative outcomes associated with a therapy or other side effects. The primary physician should be fully responsible for making decisions.

OBJECTIVE, GOOD FAITH AND SCIENTIFIC OBJECTION

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).

Matters of "good faith objection" (Sec 4743.10) exist within current Ohio law: "which violates the practitioner's, institution's, or payer's conscience as informed by the moral, ethical, or religious beliefs or principles held by the practitioner, institution, or payer." This exemption does not include matters of professional judgement. While the legislation attempts to grant broad protection from liability, simply documenting an objective good faith or scientific objection yet proceeding to dispense a medication that causes patient harm likely remains an act of malpractice by the pharmacist. Additionally, the bill creates a dual legal standard of liability between indicated and off-label dispensing that does not exist today.

HB 73 requires the pharmacist to dispense, and requires the hospital to allow the dispensing, unless the conscience clause applies or unless the pharmacist has documented that a patient has a history of life-threatening allergic reactions or there is a life-threatening contraindication.

However, in most cases, the pharmacist has no way of knowing the patient's history of life-threatening allergic reactions, or whether the contraindication is life-threatening. In addition, what constitutes "life-threatening?" Is a sickness that results in hospitalization for a month "life-threatening?" A week of hospitalization? Internal bleeding? How sick must the patient risk being before a determination is made that the condition is "life-threatening?"

Pharmacists may have legal protections associated with HB73, but there are professional and ethical convictions as well. Forcing an individual or an organization to take action is

inappropriate – pharmacists and other health care professionals should have the right based on scientific and best practice knowledge existing at the time of action – to object. Legal protections of the practitioner alone are insufficient. For any of the health care professionals: would you approve of a rule in Ohio mandating that you allow a medication to be used if it was against your moral/scientific/ethical rights just because you had liability protections? It removes the independence and freedom of individual licensed practitioners and/or hospitals to make those decisions.

CONFLICTS WITH FEDERAL LAW AND DEA INCLUDING MEDICATION RECONCILIATION

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.

HB 73 absolutely inhibits, prevents, or encumbers medication reconciliation. The term "medication reconciliation" is defined by The Joint Commission as "the process of comparing the medications a patient is taking and should be taking" with newly ordered medications" in order to resolve discrepancies or potential problems.

The goals of medication reconciliation are to obtain and maintain accurate and complete medication information for a patient and use the information within and across the continuum of care to ensure safe and effective medication use. It is intended to limit medication errors and adverse drug events. HB 73 prevents a pharmacist or hospital staff from performing medication reconciliation because HB 73 requires the prescribed drug to be dispensed/administered as prescribed. By definition "medication reconciliation" is a process that requires providers to question and object to the administration of a drug if the provider believes it will result in an adverse outcome or reaction by the patient. HB 73 completely interferes with that process by requiring the drug to be dispensed/administered, regardless of the professional perspective of the pharmacist.

In addition, HB 73 directly conflicts with state regulations governing the practice of Pharmacy, including requirements for pharmacists to conduct prospective drug utilization review prior to dispensing any prescription for the purpose of identifying: over-utilization or under-utilization; therapeutic duplication; drug-disease state contraindications; drug-drug interactions; incorrect drug dosage; drug-allergy interactions; abuse and/or misuse; inappropriate duration of drug treatment; and food-nutritional supplements-drug interactions. See OAC 4729:5-5-08

The rules required for professional judgment and the responsibilities and accountabilities of the pharmacist by OAC/ORC are in conflict with HB73. As mentioned previously, this is a concern for all health care professionals.

TRACKING MECHANISMS

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.

Today, whether indicated or off-label, prescribers practice under a standard of care and pharmacists under state law. House Bill 73 creates a classification of care and a lack of oversight that currently does not exist today.

Patients should have the same protections through regulatory boards regardless of why a medication is prescribed or used. House Bill 73 places patients at risk of harm or death by removing regulatory oversight of practice and dispensing behaviors.

Worse, it provides a new defense for rogue practitioners. For example, use of a drug for its indicated condition but at a dose that is unapproved is off-label use. Because House Bill 73 removes the regulatory board's oversight, the regulatory venue thus becomes the court of law. As currently written, courts would only have the statute to rely upon. The response given by the bill sponsor to the Chairman's question should be deeply concerning when the standard for gross negligence is judged by the volume of harm caused, or number of lives taken through one's practice of medicine.

DRUG SHORTAGES

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 health care providers are currently notified by hospitals and pharmaceutical manufacturers when a drug shortage is experienced. At that point health care 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

There is no formal mechanism in place for drug shortages, and manufacturer notification is not a process that remedies that issue. Further, the response that using "best clinical judgement on how to triage" is paradoxical. This burden clearly falls on the dispensing pharmacist who has had clinical judgement removed by the bill itself.

House Bill 73 creates a first come/first served situation during times of drug shortage for medications used off-label. Pharmacists would only find themselves in a court of law defending their choices under the numerous incidences of drug shortage, over which pharmacists have no control.

During COVID-19, the shortage of hydroxychloroquine became a textbook example of this situation. Like the proponents' vigor, you can only imagine the volume of lawsuits that would have been filed under House Bill 73 for those who felt their rights violated by the pharmacist who only had 30 pills remaining in the pharmacy and multiple prescriptions for that drug.

It is false that hospitals are notified routinely by manufacturers of shortages. More commonly these are self-discovered by the hospital, professional organizations or wholesalers.

Hospitals have structures of leadership decision-making. Further, structures such as Ethics Committees or equivalents are multidisciplinary groups that are selected/appointed to determine recommendations or actions to difficult moral, ethical, scientific decisions related to clinical patient care, such as situations with drug shortages.

Sub. HB 73 would allow individual patients or individual providers to overrule population-based, expert decisions by involved physicians, nurses, pharmacists, etc in determining how to maintain supply given expected availability, utilization, disease states. In these cases, hospital and medical leadership must manage the available product and decide how and who to allow medications for to stretch limited resources.

However, Sub. HB 73 would allow a physician – from outside of the hospital – to use the medication – if it was available here – for any patient they deemed necessary. For example, a chemotherapy agent that could be reserved for a rare cancer may be used for preference for another cancer that has many treatment options to preserve the medication. This is actually a problem even within the confines of a hospital's medical staff in this bill, as a physician could insist on access for their patient at the expense of others, so long as they could find any pharmacist to dispense it. In the case of a shortage, this could actually be a standard of care use that was deprioritized by a group determining how to best use scarce resources. Undermining institutional decisions, made collectively using many physicians, ethicists, pharmacists, and others by any single physician and pharmacist, at the expense of others, is problematic.

GOOD FAITH EFFORT TO ACQUIRE A DRUG

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)

This provision will result in litigation to determine whether a "good faith effort" was made to obtain a drug. Does "good faith" mean the hospital must call 20 other hospitals or other facilities to obtain the drug? 10? 5? 1? We suspect that a patient seeking a drug under this bill will never conclude that the hospital acted in good faith to obtain a drug unless the hospital actually obtains the drug, regardless of how extensive the hospital's efforts are. Therefore, litigation would be likely to result for courts to have to decide if the hospital acted in good faith.

OUTSIDE PROVIDERS WITHOUT PRIVILEGES AND TEMPORARY PRIVILEGES

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.

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.

Credentialing a physician within 5 days is not realistic.

HB 73 also requires the physician to "be allowed to immediately begin applying for temporary privileges with oversight, based on criteria within the hospital or inpatient facility medical staff bylaws. . ." We have never heard of the term "temporary privileges with oversight" – what does this mean? Who provides the oversight? What if a hospital does not have a category of privileges called "temporary privileges with oversight" (and we are not aware of any hospitals with such a designation).

Apart from the unrealistic timeframe in HB 73 regarding the credentialing of a physician, the precedent this bill creates for employers across Ohio is startling. In what other state or industry does the government require an employer to either employ someone or force the employer to allow someone to provide services under the auspices of the employer, or allows the individual to complain to a regulator that the employer didn't employ them (apart from discrimination claims)? The government should simply not be in the business of dictating who an employer must employ or allow to provide services in their facility or create a situation where an individual who does not get the job he or she wants because he or she does not meet the

employer's standards can file a formal complaint to a state regulator that is accessible by anyone in the general public.

We believe it is important to ensure this provider is licensed and registered for medical practice in Ohio. If not, physicians from other states could influence or gain access to hospitals as requested for patients. Further, we would expect a physician directly involved in patient care and decision making on a medication to be able to interact in-person and complete key tasks, like physical examination and patient monitoring.

The timeline for granting privileges at a hospital is not quick but is intentional and safe.

Generally, this process requires considerable paperwork including but not limited to recommendations/references, documentation of licensure and degrees, curriculum vitae or resume, background checks and review by numerous individuals internally (Chief of Service line, Medical Leadership). In many cases, those individuals signing off must verify in their role and on their license appropriate competency to practice within the hospital. In some cases, hospital medical bylaws stipulate the provider must be an employee of the hospital, which would be in conflict with HB73. In addition, credentialing and privileging only grants access, but it does not allow for training of EMR, use of systems, etc. The onboarding process includes an extensive packet and content review to safe and effective care as well as didactic training.

We feel compelled to emphasize hospitals in the US are still free enterprise. Patients can decline a therapy or transfer to seek another medical opinion or treatment. If therapies are not wanted, specific therapies are desired but not generally available or appropriate for that organization, and/or if the patient/caregiver is unsatisfied with their care, they are able to decline or redirect their care. Why would hospitals and majority of the medical staff and leaders not be able to make independent decisions on care provided?

Again, hospitals have escalation practices and policies to review medications that have not been studied, have limited evidence, and/or have controversial use within the medical community. As an organization and free enterprise entity – with many national and state regulations – can the option to transfer care not be applied to the patient or caregiver (POA)? Why is a hospital compelled to use medications not on formulary or not with approval indications? This violates not only the physician's rights to make decisions on care, but also the organization's rights to decide on care provided or not provided within their organization.

It should be added that a pre-existing relationship and in-person examination must exist prior to care in order for the physician to even be considered for any temporary privileges to prevent physicians offering these services for patients otherwise unknown to them.

This 5 day process is only access to work within the hospital. It does not account for additional training, access to systems, and compliance with policies and procedures expected of a normal employee and by other regulatory agencies. It would rely on action by other practitioners and

therefore could impact their ethical, moral, or professional convictions related to therapies or treatments. Nothing about the request should be able to interfere with medical staff bylaws or require prescriber's request for temporary privileges if requirements for privileges are not met to the hospital's standards.

SUBSTANDARD CARE

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)

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.."

It does not make any sense, and is inconsistent with well-established law, for the "standard of care" to "be best determined by the doctor who knows their patient . . ." As noted above, "standard of care" simply cannot be determined by an individual doctor vis-à-vis their patient. If every doctor can determine their own standard of care, then there is no standard at all – the standard simply varies from doctor to doctor, with no established standard at all.

There is no such thing as an individualized standard of care. The standard of care is the standard of care. If every physician or prescriber could define their own "standard of care," then there would never be a finding of medical negligence against any medical professional because all of them would simply meet their own "standard of care."

Again, as noted above, the Ohio Supreme Court has stated for decades: "The standard of care required of a medical doctor is dictated by the custom of the profession." The standard of care is simply not defined by individual physicians. To suggest otherwise is wildly out of step with well-established medical and legal standards.

OUTSIDE MEDICATIONS

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.

Requiring hospitals to permit a patient to bring their own medications into the hospital for consumption in the hospital is counter to safe patient care and not the standard followed by hospitals across the country.

Hospitals do not have any way to know if a drug is what the patient says it is. Pills are easily replicated to appear to be something they are not – such counterfeiting is partly responsible for the increase in drug overdoses around the country. Furthermore, many drugs are administered in a clear liquid form, so there is no way for a hospital to differentiate one clear liquid drug from another clear liquid drug unless the appropriate chain of custody standards that the hospital must follow is followed. Hospitals, pharmacists and other caregivers are unable to ensure the safety of drugs brought in by a patient – they can't identify the drug; can't assess whether the drug will adversely interact with another drug; can't assess whether the drug may create a serious allergic reaction; or any other outcome.

COSTS

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 health care 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.

It is outrageous to assert that health care providers follow the standard of care because they stand to gain financially from doing so. The bottom line is that providers follow the standard of care because the standard of care is based on evidence-based science and well established medical and legal standards. To suggest otherwise is reckless and irresponsible.

Furthermore, in response to the question "Does this practice currently exist anywhere in medicine," the answer is no, it does not exist anywhere in medicine because there is no requirement in any law today to require a provider to provide care that falls outside of the standard of care. HB 73 would require providers to provide care outside of the standard of care. Accordingly, when a prescriber insists on care that falls outside of the standard of care, and a pharmacist or hospital is required by law to be complicit in that care, and it is known at the outset of the care that it falls below the standard of care, it is perfectly reasonable to require the patient to be financially responsible for care resulting from the adverse outcomes that result from the substandard care that is required to be provided by HB 73.

The cost of the medication may need to be paid for in advance. In some cases, the duration of therapy (weeks of therapy) or the singular cost of the medication (e.g. gene therapy) may cost hundreds or thousands or even millions of dollars. As such, most patients could not afford these medications and most hospitals would not be able to ensure payment and take on the financial risk.

Additionally, this direction of billing a patient directly for such services violates state (ORC 4769.01) and federal law (Section 1886(d)(1)(B) of the Social Security Act). Medicare and Medicaid patients represent a large portion of patients admitted to hospitals, and hospitals are expressly prohibited from sending the patient a bill for services not covered by their insurer.

Furthermore, the Under the Consolidated Appropriations Act of 2021, billing patients even with commercial insurance may be illegal. Furthermore, the Inpatient Prospective Payment Service (and other DRG-based payment methodologies, such as APR-DRG's used by Ohio Medicaid) directly make the hospital responsible for adverse effects, extended stays, and added monitoring costs of therapies given to patients, including during that admission and for re-admissions within 30 days. As a consequence, the proposed mechanism of cost-recovery proposed is not possible under existing law, while inflicting the added expense of both the drug and its consequences on the health system.

One might argue that "if the patient demands it" that additional services could be paid for by the patient outside of a DRG. We should note the slippery slope in this, as one could imagine a situation where a hospital has "included services" but then routinely would offer add-ons on request (which may include services CMS expects in the DRG). Additionally, the physician services are included in this DRG. The physician seeking temporary privileges must as a consequence be explicitly precluded from billing for any service during the admission.

CONCLUSION

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.

The proponents of this bill have worked with a small minority of the doctors, pharmacists, lawyers and patients who are advocating for a sharp departure from the standard of care that has been recognized by the law and the practice of medicine for decades.

The overwhelming number of physicians, pharmacists, nurses and other clinicians represented by, or affiliated with, OHA, OCHA and OPA and other clinical professional societies that have expressed concerns regarding HB 73, strongly oppose HB 73 and recognize the danger it poses to Ohioans.

Cc: Members, Ohio Senate Health Committee