April 2026 – Rules & Resolutions

1) Appointment to the Home Medical Services Advisory Council

Pursuant to ORC 4752.24, the Board hereby appoints Susan Elaine Bolinski (Ravenna, OH) to the Home Medical Equipment Services Advisory Council a three-year term effective April 13, 2026.

2) Appointment of the 2026 Controlled Substances Advisory Committee:

The Board hereby appoints the following individuals as members of the 2026 Controlled Substances Advisory Committee and reauthorizes the Committee for a period of one-year from the effective date of this resolution:

Tim Bodle, Ohio Department of Behavioral Health
Dr. Thomas Gilson, Cuyahoga County Medical Examiner
Dr. Hannah Hayes, Medical Toxicologist, Nationwide Children's Hospital
Aaron Haslam, Adams County Prosecutor (Replaces Jason Holdren, Gallia County Prosecutor)
Ara Mekhjian, Ohio Attorney General's Office
Natalie Rine, PharmD, Director of Central Ohio Poison Center – Nationwide Children's Hospital
James Smith, Ohio Department of Public Safety
Dr. Dennis Summers, Ohio Department of Agriculture
Miranda Williams, Ohio Department of Health
Dr. Kenneth Yeager, Ohio Chemical Dependency Board

3) Application of OAC 4729:5-5-05 to FDA-Approved Sodium Oxybate Products Under Approved Risk Evaluation and Mitigation Strategies (REMS)

To accommodate for titration requirements, the Board hereby waives the prohibitions in OAC 4729:5-5-05 (B)(2) and (B)(4) for FDA-approved sodium oxybate products that are subject to an approved Risk Evaluation and Mitigation Strategy. As a condition of this exception, all pre-printed forms shall be designed to require the inclusion of a diagnosis code in accordance with

OAC 4729:5-5-15 (B)(14). This exception does not apply to any non-FDA approved products, including any dangerous drugs that are compounded.

4) Third-Party Intermediary Approval Per OAC 4729:5-3-11

The Board hereby waives the third-party intermediary approval process pursuant to paragraph (C) of OAC 4729:5-3-11. While the Board is waiving approval, licensees are expected to comply with all other applicable requirements of the rule, including the following:

> *(4) A non-controlled prescription may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image if the transmission is conducted by means of a system that meets the prescription requirements of rule 4729:5-5-15 of the Administrative Code and either of the following apply.*
>
> *(a) The prescription transmission system operates within a closed-system. A closed system includes any system whereby prescription information is transmitted directly between:*
>
> *(i) Any division, subsidiary, parent or affiliated or related company under common ownership and control; or*
>
> *(ii) One or more contracted entities. Contracted means having a written agreement (to include business associate agreements) between one or more prescribers and a pharmacy and shall not include a third-party intermediary unless otherwise approved by the board.*
>
> *(b) The transmission of a prescription for compounded total parenteral nutrition for dispensation by a pharmacy. (Added by Board Resolution on 11/3/2025)*
>
> *(5) A non-controlled prescription may be converted into a computer-generated fax by a third-party intermediary only if the conversion is necessitated by a temporary telecommunication outage of the third-party intermediary or receiving pharmacy.*

The Board also approves the filing of amendments to OAC 4729:5-3-11 as follows:

Rule 4729:5-3-11 | Transmission of outpatient prescriptions.

(A) Oral transmission by a prescriber or a prescriber's agent of an original outpatient prescription authorized by a prescriber shall comply with the requirements of rule 4729:5-5-15 of the Administrative Code. For any oral outpatient prescription transmitted by an agent of a prescriber, the prescriber's agent must provide the agent's first and last name when transmitting the prescription. An oral prescription may be transmitted by a prescriber or prescriber's agent to a recording device or voice mail service. **All oral prescriptions transmitted by a prescriber or prescriber's agent shall be documented in the patient's medical record by the issuing prescriber.**

(B) Original written outpatient prescriptions shall be authorized and signed by a prescriber, **using a manual, wet-ink signature,** ~~**in the same manner as the prescriber would sign a check or legal document**~~, and may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy.

(1) The facsimile of the prescription must include the identification number of the facsimile machine ~~**which**~~ **that** is used to transmit the prescription, the full name of the prescriber, and, if applicable, the full name of the prescriber's agent transmitting the prescription to the pharmacy.

(2) The prescription must comply with the requirements of rule 4729:5-5-15 of the Administrative Code.

(3) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the location where it was issued for three years from the date of issuance. Following the successful transmission of the prescription, the word "VOID" or "FAXED" shall be written or stamped on the face of the original prescription in a manner that does not destroy any of the original information contained on the prescription.

(4) Outpatient prescriptions for schedule II controlled substances may be transmitted by facsimile in accordance with 21 C.F.R. 1306.11 (~~**5/1/2019**~~ **March 31, 2010**) and shall meet the facsimile requirements of this rule.

(C) Outpatient prescriptions may be transmitted by means of an electronic prescription transmission system that complies with the prescription requirements in rule 4729:5-5-15 of the Administrative Code.

(1) An outpatient prescription transmitted by means of an electronic prescription transmission system shall include the full name of the prescriber's agent transmitting the prescription.

(2) A controlled substance outpatient prescription shall only be transmitted by means of an electronic prescription transmission system if the system complies with 21 CFR 1311 (**~~5/1/2019~~April 1, 2026**).

(3) Except as provided in paragraphs (C)(4) and (C)(5) of this rule, no prescriptions may be transmitted by means of an electronic prescription transmission system that converts the prescription into a **computer-generated or scanned fax or image** **~~computer-generated images, fax or scanned image~~**.

(4) A non-controlled prescription may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image if the transmission is conducted by means of a system that meets the prescription requirements of rule 4729:5-5-15 of the Administrative Code and either of the following apply:

(a) The prescription transmission system operates within a closed-system. A closed system includes any system whereby prescription information is transmitted directly between:

(i) Any division, subsidiary, parent or affiliated or related company under common ownership and control; or

(ii) One or more contracted entities. Contracted means having a written agreement (to include business associate agreements) between one or more prescribers and a pharmacy and shall not include a third-party intermediary unless otherwise approved by the board.

(b) The transmission of a prescription for compounded total parenteral nutrition for dispensation by a pharmacy.

~~**(4) A non-controlled prescription may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image if all the following apply:**~~

~~**(a) The transmission is conducted by means of a board approved system that meets the prescription requirements of rule 4729:5-5-15 of the Administrative Code.**~~

~~**(b) The prescription transmission system operates within a closed system. A closed system includes any system whereby prescription information is transmitted directly between:**~~

~~**(i) Any division, subsidiary, parent, or affiliated or related company under common ownership and control; or**~~

~~**(ii) One or more contracted entities. Contracted means having a written agreement (to include business associate agreements) between one or more prescribers and a pharmacy and shall not include a third-party intermediary unless otherwise approved by the board.**~~

(5) A non-controlled prescription may be converted into a computer-generated fax by a ~~**board approved**~~ third-party intermediary only if the conversion is necessitated by a temporary telecommunication outage of the third-party intermediary or receiving pharmacy. **Unless otherwise approved by the board, the telecommunications outage shall not last more than seventy-two continuous hours.**

(D) Outpatient prescriptions shall not be transmitted via electronic mail (e-mail) and shall be transmitted in compliance with 45 CFR Part 160 (April 1, 2026) and 45 CFR Part 164 (April 1, 2026).

Ohio Board of Pharmacy - Hearing Summary Report

Hearing Date: 3/30/2026

Rule Number(s):

Rule Number	Type	Description
4729:9-1-01.1	**New**	**Mitragynine-Related Compounds.**

List organizations or individuals giving or submitting testimony before, during, or after public hearing and indicate the rule number(s) in question.

Support the Rule

- Mayor of the City of Troy, Ohio
- Global Kratom Coalition
- The Ohio Council of Behavioral Health and Family Services Providers
- Ohio Alliance of Recovery Providers
- Griffin Ambitions LTD
- Eight individual commenters

Requests a Complete Kratom Ban (e.g., this rule does not go far enough)

- One individual commenter

Oppose the Rule

- Reason Foundation (Los Angeles, CA)
- Holistic Alternative Recovery Trust (HART) (Louisville, KY)
- One individual commenter (Received April 8, 2026)

Consolidated Summary of Comments Received

Supporters:

- Support the Board drawing a hard line against synthetic kratom-related compounds; chemically altered kratom-related products; isolated or concentrated 7-hydroxymitragynine products; and deceptive formulations that fundamentally alter the character and risk profile of traditional natural leaf.
- Highlighted the negative health impacts of kratom-related products due to their widespread availability at gas stations and other retailers. With one commenter noting: “The human cost is far too high to justify the profits of those who sell it.”
- Concerns about the accessibility of these compounds to vulnerable populations, including individuals in recovery and young people, who may perceive it as a benign or “natural” product. Scheduling kratom as a Schedule I substance would reduce availability and send an important public health message about the risks it poses.
- Those representing treatment providers point to a growing number of patients being treated for detoxification or treatment related to kratom and kratom-related compounds.
- Others representing natural kratom growers support the rule because it includes an explicit carveout for natural kratom leaf in vegetation form. They further recommend that the Board further clarify the rule’s scope to ensure it is limited to synthetic and chemically altered kratom-related compounds and does not inadvertently capture non-synthetic kratom products outside the intended vegetation form carveout.

Requests a Complete Kratom Ban (e.g., this rule does not go far enough):

- One commenter said that the Board’s rule does not go far enough. They noted that their son passed from natural whole leaf powder.

Oppose the Rule:

- The Board's supporting evidence fails to clearly establish an imminent public health hazard and focuses on the consequences of an unregulated market rather than inherent pharmacological risk.
- The Board's respiratory depression argument rests entirely on rodent IV studies; no human clinical trial has confirmed these compounds as having respiratory effects equivalent to those of full opioids.

- The Board cites mislabeling and contamination as serious concerns. These problems are real, and they are products of an unregulated market. Commercial products have been found to contain undisclosed compounds and unlabeled alkaloids.
- The Board's lack of a medical use finding for MP is premature. In November 2024, NIDA awarded Sparian Biosciences a $19.5 million, five-year grant to develop SBS-226, an MP-derived compound, through Phase 1 clinical trials for opioid use disorder treatment. The scientific process to determine whether MP has accepted medical use has not concluded.
- Proposed bans on kratom and its natural components, such as mitragynine and 7-hydroxymitragynine (7-OH), undermine consumer choice and autonomy and do not provide a rationale for how banning kratom-derived supplements would serve the interest of public health.
- Like many dietary supplements or functional foods, no category of kratom products is inherently without some risk.
- The issue is whether moving forward with a compound-specific Schedule I classification at this stage (i) effectively resolves a live policy question that is currently being developed legislatively, and (ii) does so in a way that does not address the broader and more adaptive category of synthetic and high-potency products the legislation is designed to regulate. For example, if mitragynine is scheduled, manufacturers can shift to alternative alkaloids or modified compounds that produce similar or greater effects but fall outside the scope of the rule, requiring a new rulemaking cycle for each iteration. In other words, a compound-specific rule targets a fixed input, while the market continues to evolve around it - for example, a product that is compliant on the day a rule is adopted can be reformulated shortly thereafter to produce similar effects using a slightly different chemical profile, placing it outside the rule's scope until a new regulatory action is taken.

Incorporated Comments into Rule(s)

- The rule was not amended based upon the feedback provided during the public hearing.

Comments not Incorporated into Rule(s)

- The Board did not incorporate a request from natural kratom producers to further clarify the rule's scope to ensure it is limited to synthetic and chemically altered kratom-related compounds and does not inadvertently capture non-synthetic kratom products outside the intended vegetation form carveout. Paragraph (A)(4) of the rule is clear that all kratom products that are sold in natural vegetative form and in accordance Chapter 3715. of the Revised Code are not impacted by this rule. This paragraph was specifically modified during the Common Sense Initiative process to address these concerns.
- The Board did not incorporate the comment that suggests the Board ban all forms of kratom. In January 2026, the Board authorized the filing of OAC 4729:9-1-01.2. This rule classifies the primary compound in kratom (known as mitragynine) as a Schedule I controlled substance. This covers all kratom products including natural plant material and extracts from natural plant material. This rule is currently under review by the Board and the Common Sense Initiative.
- The Board contends that legislative action is not precluded by this rule. In fact, a recent quote from Rep. Roy Klopfenstein, R-Haviland — who chairs the House Agriculture Committee that is reviewing the proposal from Rep. Mike Odioso, R-Cincinnati, and Rep. Brian Lorenz, R-Powell — said in an interview that JCARR's decision "will influence what we do as a committee as far as synthetic versus natural."
- Additionally, the Board does not see this a compound-specific framework. The rule language covers a broad range of mitragynine-related compounds.

Response to Comments Regarding the Scientific Applicability of the Rule(s)

Comment Summary	Board Response
The Board's supporting evidence fails to clearly establish an imminent public health hazard and focuses on the consequences of an unregulated market rather than inherent pharmacological risk. **Proposed bans on kratom and its natural components, such as mitragynine and 7-hydroxymitragynine (7-OH), undermine consumer choice and autonomy and do not provide a rationale for how banning kratom-derived supplements would serve the interest of public health.** **Like many dietary supplements or functional foods, no category of kratom products is inherently without some risk.**	Ohio courts have recently affirmed the Board's expertise and analysis to review scientific evidence pertaining to these compounds. In the denial of a temporary restraining order for OAC 4729:9-1-01.1, the courts determined the Board "relied on an appropriate factual record." It further noted that the Board is comprised of professionals who can take certain study limitations into account and that it was not unreasonable to rely on information provided by the FDA. (See Case No. 26 CV 403, Holistic Alternative Recovery Trust v. State of Ohio Board of Pharmacy). The commenter discusses the need to prove an "imminent public health hazard." However, this standard is not applicable, as ORC 3719.44 (C) states: *The board may add or transfer a compound, mixture, preparation, or substance to schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.* These comments also ignore the existing science, data, case reports, and testimony available about the dangers posed by these compounds, including, but are not limited to, the following: ▪ In various preclinical studies, 7-OH (a mitragynine-related compound) demonstrates greater potency than classical opioids warranting control in Schedule I. For

	example, 7-OH produces respiratory depression with more than 3-fold greater potency than morphine. ▪ Preemptive action is justified for mitragynine-related compounds that are engineered in labs to enhance opioid potency. For example, MGM-15 shows greater hMOR and hDOR binding affinities than 7-OH, indicating the potential for higher opioid effects and risks. ▪ Partial opioid agonists (e.g., buprenorphine) have been used as treatment for kratom and kratom-related compounds. ▪ Comments from clinicians also cite the dangers of these compounds. For example, a prominent clinician in Northeast Ohio commented that they have "…been admitting ALMOST AS MANY patients per week withdrawing from Kratom and it's analogues as I am from Fentanyl for at least the past year." ▪ The FDA has received reports of the harmful effects associated with 7-OH products. These effects include addiction, anxiety, depression, gastrointestinal distress, insomnia, seizures and withdrawal symptoms – such as restlessness, body aches, fatigue, irritability, and cold sweats. ▪ Manufacturers warn of the dangers of their own products, including the risk of death (see Figure 1 and Figure 2 in this document). ▪ The rule does not prohibit any mitragynine-related compounds that are approved for use by the FDA. The rule itself includes exceptions for FDA-approved products.

	▪ One commenter noted that kratom products can "carry some risk." This is downplayed by the real-world implications of the availability of this product. A central Ohio man recently took his own life after becoming addicted to synthetic kratom. Bank statements show the individual was purchasing 7-OH multiple times per week at a small-town gas station for $100-$200 at a time. ▪ A March 2026 analysis of National Poison Control System data by the CDC found an increase of approximately 1,200% in kratom-related exposure reports (from 258 to 3,434), including a marked surge in 2025.
The Board's respiratory depression argument rests entirely on rodent IV studies; no human clinical trial has confirmed these compounds as having respiratory effects equivalent to those of full opioids.	▪ By the commenter's own admission, there are no human clinical trials to demonstrate the safety and efficacy of these compounds. ▪ Commenters seem to advocate for the use of these products as medicine (they cite the treatment of pain, anxiety, and depression) without requiring the steps necessary to determine risk/benefit and proper dosing through the established FDA processes. ▪ Opponents of the rule seem to focus on claims of respiratory depression as the only rationale for placement of mitragynine-related compounds in Schedule I. ▪ The Board is also concerned about the negative impact of the availability of these products on the quality of life for Ohioans, including use by children. The Board has numerous examples provided by Ohioans demonstrating how the availability of these

	addictive substances has a negative impact on overall quality of life. ▪ For example, one commenter stated during the CSI comment process: *Keeping 7-oh illegal is the best thing to ever happen. i've watched my husband struggle with a kratom & 7-oh addiction that lead us to a bad spot. It gave him chest pains, he lost weight, was very cool pale & diaphoretic. It is a threat to everyone's well being & life. I also know several stories of people dying & having a heart attack secondary to using this substance. I have watched my husband withdrawal and relapse several times trying to better his life & it's been very heart breaking to watch it all unfold. It was so readily available which he admitted made the addiction harder to stop. I've watched and read so many stories of others losing people due to the mental strain of withdrawal that they committed suicide. I am also a nurse and pretty well rounded to experiencing drug withdrawal and you would have thought you were watching somebody withdrawal from heroin but really it was 7-oh. it's disguised to be "natural, safe & ok" because it's from a leaf. it's all a scam to get you hooked into it & people that sell this crap are more focused on the money lost than people out here dying & battling addiction from it.* ▪ This is confirmed by clinical presentations of mitragynine-related compounds, which include euphoria, sedation, respiratory depression, and opioid-like withdrawal syndromes, with users acknowledging its significant addiction potential.

The Board cites mislabeling and contamination as serious concerns. These problems are real, and they are products of an unregulated market. Commercial products have been found to contain undisclosed compounds and unlabeled alkaloids.	▪ The commenter acknowledges the real risks posed by an unregulated market, including the lack of testing as risk-factor to the public health. ▪ It should be noted that after Utah developed a regulatory scheme to maintain over-the-counter access to kratom, overdose deaths related to kratom and treatment for kratom use disorder persisted. One emergency room physician reported patients sharing that they "had no idea it was just like a narcotic," and that his patients experience the same withdrawal symptoms as those withdrawing from narcotics. ▪ While the commenter can advocate for regulation to address some of the concerns raised by the Board, it does not change the real-world risk factors currently posed by widespread availability of these compounds and their affinity to bind to the opioid receptors of the brain. ▪ It should also be known that the FDA specifically notes that "there is no food additive regulation that authorizes the use of 7-OH or kratom extract in food."
The Board's lack of a medical use finding for MP is premature. In November 2024, NIDA awarded Sparian Biosciences a $19.5 million, five-year grant to develop SBS-226, an MP-derived compound, through Phase 1 clinical trials for opioid use disorder treatment. The scientific process to determine	▪ While this comment pertains to what is understood to be a derivative of sbs-226, sbs-226 is not mitragynine pseudoindoxyl (MP). Therefore, it is not accurate to equate the two compounds as small changes in chemical structures can significantly impact how a drug affects the human body. ▪ The existence of a Phase I clinical trial does not prove that a compound is safe and effective. That determination is made

whether MP has accepted medical use has not concluded.	following the completion of a Phase III clinical trial and approval of new drug application by the FDA. ▪ Phase I clinical trials are concerned primarily with establishing a new drug's safety and dose range in about 20-100 healthy volunteers. ▪ The Board of Pharmacy issues licenses to laboratories and other facilities engaged in clinical trials, including Schedule I controlled substances. Therefore, this action does not stymie any possible research conducted in the state. ▪ This is supported by the fact that there are over 200 clinical trials studying the effects of psilocybin, including at least 7 in Ohio. ▪ Product labeling for mitragynine-related compounds, including MP, also includes statements acknowledging the ability of these compounds to produce psychic or physiological dependence including: ○ **HEALTH AND SAFETY WARNING:** This product contains psychoactive alkaloids, which may include mitragynine, 7-hydroxymitragynine, and mitragynine pseudoindoxyl, which interact with the human opioid system. These alkaloids are active at all known opioid receptors - mu, kappa and delta - each affecting them in various ways and with various potencies. ○ **WARNING:** This product may be habit-forming. Regular use can lead to physical and/or psychological dependence, addiction, and withdrawal symptoms may occur upon

	discontinuation. If you suspect addiction, seek medical help immediately. ○ **Disclaimers:** By using this product, you accept full responsibility for any adverse events or health complications that may arise from its use. Manufacturers & Resellers assume no responsibility or liability for the use or misuse of this product. Alkaloids may interact distinctively with pain relief remedies, opioids, anxiolytics, antidepressants, and soothing drugs, as it can modify certain bodily processes. Consult with your physician prior to using alkaloids, especially if you take any medications. It is important to note that the use of alkaloids with alcohol or sleep-inducing drugs may exacerbate their effects, therefore it is not recommended. For safety reasons, it is recommended you abstain from combining alkaloids with other substances. Although there aren't studies conclusively showing addiction related to alkaloids, there are anecdotal reports of people developing an addiction to alkaloid products. If you feel you are developing an addiction to this or any product, consult a physician or an addiction center immediately. Do not use this product if pregnant or nursing. Do not operate heavy

	machinery, watercraft or motor vehicles while using. Not for sale to minors, 21+ only!

Figure 1. Warning Label of a Kratom-related Product

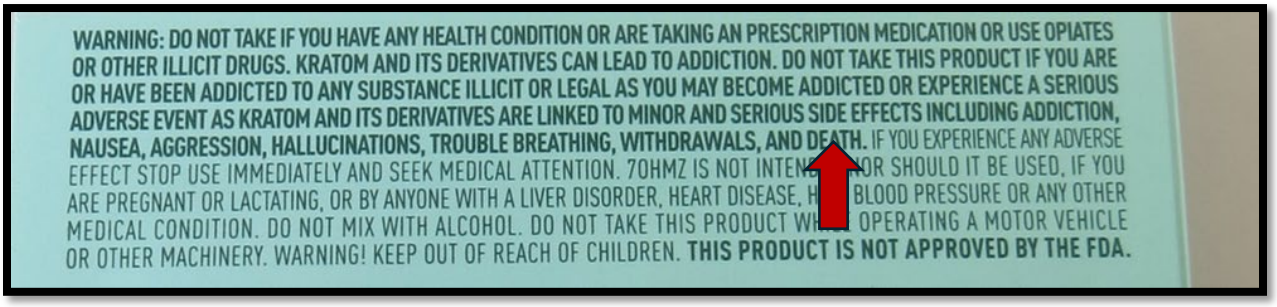

Figure 2. Sample Warning Label for Mitragynine-Pseudoindoxyl

For Filing with JCARR:

Rule 4729:5-2-01 | Responsible person - terminal distributor. (NEW – Replaces Current Rule)

(A) For an outpatient pharmacy licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-5 of the Administrative Code:

(1) Only a pharmacist may be the responsible person for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs.

(2) Except as provided for in this paragraph, a pharmacist shall not serve as the responsible person for more than one outpatient pharmacy. A pharmacist may serve as the responsible person for up to two outpatient pharmacies if the following requirements are met:

(a) The pharmacist can meet the supervision requirements in paragraph (A)(5) or (A)(6) of this rule;

(b) The outpatient pharmacies have not been disciplined for any significant theft or loss of dangerous drugs within the preceding twelve months;

(c) The outpatient pharmacies have not been disciplined for violation of rule 4729:5-5-02 and all subsequent rules thereunder within the preceding twelve months;

(d) Neither of the outpatient pharmacies are open more than 20 hours per day;

(e) The pharmacist seeking to be the responsible person has been licensed to practice pharmacy in this state for at least one year;

(f) The pharmacist is not currently on probation or is otherwise restricted from serving as the responsible person on multiple licenses pursuant to a settlement agreement or order of the board.

(3) The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in

division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

(4) The terminal distributor of dangerous drugs and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(5) Except as provided in paragraphs (A)(6) or (A)(7) of this rule, the pharmacist serving as the responsible person shall work a minimum of twenty hours per week at the pharmacy or pharmacies where the pharmacist serves as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(6) The pharmacist serving as a responsible person of a pharmacy that is not operational for forty hours per week shall work a minimum of fifty percent of the total hours the pharmacy is open per week, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(7) The Board's executive director, or the director's designee, may grant approval to allow for a pharmacist to temporarily serve as the responsible person for two outpatient pharmacies without meeting the supervision requirements in paragraphs (A)(5) or (A)(6) of this rule if the following are met:

(a) The pharmacy can document that a death, incapacity, emergency medical leave (does not include planned medical leave), unexpected resignation, or discharge of the responsible person has occurred.

(b) The pharmacy can document that current staffing is not sufficient to meet the supervision requirements of this rule.

(c) The temporary approval is valid for thirty-one days from the date it is approved by the board's executive director or the director's designee and cannot be renewed.

(d) On or before the end of the temporary approval issued by the board, the pharmacy shall designate a responsible person that meets the requirements set forth in this rule. Upon designation of a new responsible person, the temporary approval issued by the board is no longer valid.

(e) The responsible person shall either:

(i) For a pharmacy operational at least forty hours per week: work a minimum of ten hours per week at each pharmacy; or

(ii) For a pharmacy that is not operational for forty hours per week: work a minimum of twenty-five percent of the total hours the pharmacy is open per week.

(f) The requirements of paragraphs (A)(2)(b) through (A)(2)(f) can be met.

(g) All requests made pursuant to this paragraph shall be submitted, in a manner determined by the board, no later than ten business days after the death, incapacity, commencement of emergency medical leave, unexpected resignation, or discharge of a pharmacist serving as the responsible person.

(B) For an institutional pharmacy, including an institutional outpatient pharmacy, licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-9 of the Administrative Code:

(1) Only a pharmacist may be the responsible person for an institutional pharmacy licensed as a terminal distributor of dangerous drugs.

(2) Except as provided in paragraphs (B)(7) of this rule, a pharmacist may serve as the responsible person on no more two pharmacies, either outpatient or institutional, licensed as terminal distributors of dangerous drugs if both pharmacies are located on a campus, as defined in section 4729:5-1-01 of the Administrative Code, and the pharmacist is not currently on probation or is otherwise restricted from serving as the responsible person on multiple licenses pursuant to a settlement agreement or order of the board.

(3) The responsible person shall be responsible for all of the following:

(a) The practice of the profession of pharmacy performed within the institutional pharmacy and, if applicable, the institutional facility, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

(b) The development, implementation, supervision, and coordination of all services provided by the institutional pharmacy.

(c) In conjunction with the appropriate interdisciplinary committees, the development of written policies and procedures which are consistent with this division of the Administrative Code and other applicable federal and state laws, regulations, and rules governing the legal distribution of drugs, adherence to these policies and procedures in order to provide for the safe distribution of drugs in all areas of the institutional facility, and making readily retrievable a current copy of these written policies and procedures.

(4) The terminal distributor of dangerous drugs and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(5) Except as provided in paragraphs (B)(6) and (B)(7) of this rule, the pharmacist serving as the responsible person shall comply with one of the following:

(a) For a pharmacy that is operational for forty or more hours per week, work a minimum of twenty hours per week at the pharmacy or pharmacies where the pharmacist serves as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(b) For a pharmacy that is not operational for forty hours per week, work a minimum of fifty percent of the total hours the pharmacy is open per week, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(c) Conduct an on-site, in-person visit of the pharmacy where they serve as the responsible person on a quarterly basis pursuant to the requirements of paragraph (G) of this rule. The pharmacy shall be owned and operated by the institutional facility and shall be located on the campus or directly adjacent to the campus of the institutional facility, as defined in paragraph (I) of this rule.

(6) The board's executive director, or the director's designee, may grant approval to allow for a pharmacist to temporarily serve as the responsible person for two pharmacies, either outpatient or institutional, without meeting the supervision requirements in paragraphs (B)(5)(a) or (B)(5)(b) of this rule if the following are met:

(a) The pharmacy can document that a death, incapacity, emergency medical leave (does not include planned medical leave), unexpected resignation, or discharge of the responsible person has occurred.

(b) The pharmacy can document that current staffing is not sufficient to meet the supervision requirements of this rule.

(c) The temporary approval is valid for thirty-one days from the date it is approved by the board's executive director or the director's designee and cannot be renewed.

(d) On or before the end of the temporary approval issued by the board, the pharmacy shall designate a responsible person that meets the requirements set forth in this rule. Upon designation of a new responsible person, the temporary approval issued by the board is no longer valid.

(e) During the period that the temporary approval is valid, the responsible person shall either:

(i) For a pharmacy operational at least forty hours per week: work a minimum of ten hours per week at each pharmacy; or

(ii) For a pharmacy that is not operational for forty hours per week: work a minimum of twenty-five percent of the total hours that each pharmacy is open per week.

(f) The requirements of paragraph (B)(2) can be met.

(g) All requests made pursuant to this paragraph shall be submitted, in a manner determined by the board, no later than ten business days after the death, incapacity, commencement of emergency medical leave, unexpected resignation, or discharge of a pharmacist serving as the responsible person.

(7) The requirements of paragraphs (B)(2) and (B)(5) of this rule do not apply to terminal distributors of dangerous drugs with a pharmacy supplied contingency stock classification. An institutional pharmacy shall develop and implement policies and procedures on the management of pharmacy supplied contingency stock to ensure compliance with the requirements of Chapter 4729 of the Revised Code and all applicable rules adopted thereunder.

(C)

(1) For a non-resident pharmacy licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-8 of the Administrative Code:

(a) Only a pharmacist may be the responsible person for a non-resident pharmacy licensed as a terminal distributor of dangerous drugs.

(b) A pharmacist shall not serve as the responsible person for more than one non-resident pharmacy licensed as a terminal distributor of dangerous drugs, unless the non-resident pharmacies are located on a campus as defined in section 4729:5-1-01 of the Administrative Code.

(c) The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

(d) Unless the licensee can demonstrate that such compliance would cause the non-resident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, the terminal distributor of dangerous drugs and all pharmacists on duty are

responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

(e) The non-resident pharmacy shall comply with the supervision requirements for the responsible person, pharmacist/person-in-charge, or any other similar licensure requirement of the state in which the pharmacy is operating. Any absence of the responsible person from the non-resident pharmacy that exceeds 31 days requires the designation of a new responsible person.

(2) For a non-resident terminal distributor of dangerous drugs that is not a pharmacy:

(a) Only a pharmacist or prescriber may be the responsible person.

(b) A pharmacist or prescriber shall not serve as the responsible person for more than one non-resident terminal distributor of dangerous drugs, unless the non-resident terminal distributor is on a campus as defined in section 4729:5-1-01 of the Administrative Code.

(c) The responsible person shall be responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, and security and control of dangerous drugs, and maintaining all drug records otherwise required.

(d) Unless the licensee can demonstrate that such compliance would cause the non-resident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, the terminal distributor of dangerous drugs and all pharmacists and prescribers on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs.

(e) The non-resident terminal distributor shall comply with the supervision requirements for the responsible person, pharmacist/person-in-charge, or any other similar licensure requirement of the state in which the terminal distributor is operating. Any absence of the responsible person from the terminal distributor that exceeds 31 days requires the designation of a new responsible person.

(D) For locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code:

(1) Only a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may be the responsible person for a category III terminal distributor of dangerous drugs with a pain management classification license as defined in section 4729.552 of the Revised Code.

(2) The physician serving as the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with a pain management clinic classification shall work a minimum of eight hours per week at pain management clinic where the physician serves as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(3) The responsible person shall submit to a criminal records check in accordance with section 4776.02 of the Revised Code.

(4) The responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code shall meet one of the following requirements:

(a) Hold current subspecialty certification in pain management by the American board of medical specialties, or hold a current certificate of added qualification in pain management by the American osteopathic association bureau of osteopathic specialists;

(b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists;

(c) Hold current board certification by the American board of pain medicine;

(d) Hold current board certification by the American board of interventional pain physicians; or

(e) Meet both of the following:

(i) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists; and

(ii) Demonstrate conformance with the minimal standards of care in accordance with rule 4731-29-01 of the Administrative Code.

(5) The pain management clinic with a category III terminal distributor of dangerous drugs license and all licensed health professionals practicing at that location are responsible for compliance with all state and federal laws, regulations, and rules governing the operation of a pain management clinic and prescribing of controlled substances.

(E) For an emergency medical service (EMS) organization licensed as a terminal distributor of dangerous drugs in accordance with chapter 4729:5-14 of the Administrative Code:

(1) Only the following may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for an EMS organization:

(a) A physician licensed in accordance with Chapter 4731 of the Revised Code;

(b) A pharmacist licensed in accordance with Chapter 4729 of the Revised Code; or

(c) An advanced emergency medical technician or paramedic issued a certificate to practice in accordance with Chapter 4765 of the Revised Code.

(2) If the responsible person is a physician licensed in accordance with Chapter 4731 of the Revised Code, that individual may also serve as EMS organization's medical director pursuant to Chapter 4729:5-14 of the Administrative Code. If the responsible person is not a physician, the EMS organization shall designate a medical director that meets the requirements of Chapter 4729:5-14 of the Administrative Code.

(3) A responsible person for an EMS organization shall either:

(a) Work a minimum of twenty hours per week at the location licensed as a terminal distributor of dangerous drugs where they serve as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(b) Conduct an on-site, in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis pursuant to the requirements of paragraph (G) of this rule.

(F) Except as otherwise provided in paragraphs (A), (B), (C), (D), and (E) of this rule, a responsible person of a terminal distributor of dangerous drugs shall comply with any of the following:

(1) Work a minimum of eight hours per month at the location licensed as a terminal distributor of dangerous drugs where they serve as the responsible person, except when absent due to authorized leave. Authorized leave includes a scheduled vacation, illness, federal or state holiday, or temporary leave of absence lasting no more than 31 calendar days.

(2) Conduct an on-site, in-person visit of the terminal distributor where they serve as the responsible person on a quarterly basis pursuant to the requirements of paragraph (G) of this rule.

(3) For terminal distributors owned and operated by an institutional facility, conduct an on-site, in-person visit of the terminal distributor by a pharmacist employed by the institutional facility on a quarterly basis pursuant to the requirements of paragraph (G) of this rule.

(G) An on-site, quarterly in-person visit as described in this rule shall consist of the following:

(1) A process to review and document compliance with the following requirements:

(a) Drug security;

(b) Drug purchases and sales;

(c) Compounding in accordance with division 4729:7 of the Administrative Code, if applicable;

(d) Record keeping;

(e) Temperature monitoring;

(f) Storage and disposal of adulterated or expired drugs; and

(g) Any other requirements of Chapters 4729., 3719., and 3715. of the Revised Code and all applicable rules adopted thereunder.

(2) Except as provided in paragraph (G)(3) of this rule, all on-site, in-person visits shall be documented by the responsible person.

(3) For on-site, in-person visits conducted in accordance with paragraph (F)(3) of this rule, the pharmacist shall document the visit and such documentation shall be provided to the responsible person no later than three business days from the date of visit.

(4) All documentation required by this paragraph shall be maintained for three years from the date of visit. A copy of this documentation shall be maintained at the terminal distributor of dangerous drugs where the visit was conducted for immediate on-site inspection by an agent, officer, or inspector of the board.

(5) A terminal distributor of dangerous drugs shall develop and implement a policy that requires the correction of any violations identified as part of an on-site, in-person visit.

(H) For all locations licensed as a terminal distributor of dangerous drugs:

(1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.

(2) When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board and in accordance with all applicable provisions of Chapter 4729. of the Revised Code. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code.

(3) A complete inventory, pursuant to 21 CFR 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-07 of the Administrative Code, shall be taken of the controlled

substances on hand by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs.

(4) The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs.

(5) A responsible person shall hold a valid Ohio license, registration, or certification from an occupational licensing board as defined in section 4798.01 of the Revised Code. This requirement does not apply to terminal distributors of dangerous drugs that do not require the responsible person to hold a professional license, registration, or certification in accordance with the resolution issued by the board in pursuant to paragraph (H)(7) of this rule.

(6) The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

(7) The board of pharmacy shall issue a resolution providing the credential types required for the responsible person of each classification/business type of terminal distributor of dangerous drugs license. Only individuals that meet the specified credentials may be the responsible person for that classification/business type. The resolution shall be updated as necessary and shall be made available on the board's web site (www.pharmacy.ohio.gov).

(I) Unless otherwise approved by the board, a terminal distributor shall not have a responsible person who:

(1) Has been denied the right to work in any facility or serve as the responsible person by the state board of pharmacy as part of an official order of the board.

(2) Has been denied the right to work in such a facility by another professional licensing board/agency as part of an official order of that board/agency.

(3) Has committed an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(4) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(5) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(6) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(7) Is addicted to or abusing alcohol or drugs.

(8) Has been excluded from participation in medicare or a state health care program.

(9) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(10) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension, probation, surrender, or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(l) As used in this rule:

(1) “Campus” has the same meaning as in rule 4729:5-1-01 of the Administrative Code.

(2) "Directly adjacent" means any adjacent property that is within one mile (5,280 feet) from all or a part of the campus of an institutional facility.

(1) Maintain a record keeping system that will provide accountability for the receipt, disposal, and return of all dangerous drugs dispensed by the pharmacy in accordance with this division of the Administrative Code.

(2) Unless donated to a drug repository program pursuant to section 3715.87 of the Revised Code, a dangerous drug that is not distributed or administered to a patient shall either:

(a) Be returned to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code.

(3) Except for terminal distributors of dangerous drugs who are pharmacies, ~~Only~~only receive drugs from the dispensing pharmacy if there is clear and convincing evidence that the delivery of a dangerous drug directly to the patient would result in:

(a) Danger or harm to public health or safety; or

(b) Danger or harm to the patient without increased involvement by a health care professional in the patient's drug therapy.

(4) The location acknowledges that any patient specific dangerous drug dispensed by a pharmacy is the property of that patient, except that a dangerous drug that is not distributed or administered to that patient within six months of dispensation shall be deemed abandoned. A terminal distributor of dangerous drugs may do any of the following with an abandoned drug:

(a) Return the drug to the dispensing pharmacy for disposal or, if applicable, returned to stock;

(b) Be disposed of in accordance the applicable rules set forth in this division of the Administrative Code;

(c) Donate to a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code. For the purposes of meeting the requirements under division (H) of section 3715.873 of the Revised Code and rule 4729:5-10-06 of the Administrative Code, a terminal distributor of dangerous drugs that possesses an abandoned drug shall be deemed as the owner of the drug for the sole purpose of providing consent for the drug's donation to a drug repository program; or

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Rule 4729:6-1-01 | Definitions - distributors of dangerous drugs. (AMEND)

As used in this division:

(A) "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code:

(1) Wholesale distributors of dangerous drugs, including:

(a) Brokers; and

(b) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

(B) "Abandoned application" means an application submitted for licensure in accordance with this division that meets the criteria in paragraph (B)(1) of this rule. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If the application is abandoned, the applicant shall be required to reapply for licensure, submit the required fee, and comply with the licensure requirements in effect at the time of reapplication.

(1) An application shall be deemed abandoned if any of the following apply:

(a) An applicant fails to demonstrate compliance with rule 4729:6-2-01 of the Administrative Code and the applicable licensing rules pursuant to this division within ninety days of receipt of a completed application. The applicant may submit a request to the executive director or the director's designee for a one-time, ninety-day extension.

(b) An applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board.

(c) An applicant that fails to demonstrate compliance with appropriate security and control rules pursuant to this division of the Administrative Code. The applicant may submit a request to the executive director or the director's designee for a one-time, ninety-day extension.

(2) An application shall not be deemed abandoned if the application is subject to any of the following:

(a) An administrative proceeding; or

(b) If there is discipline pending against the applicant.

(C) "Access to drug stock" includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, information technology or other staff that may need limited supervised access to areas where dangerous drugs or drug enforcement administration controlled substance order forms are stored.

(D) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section 3719.011 of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

(E) "Adulterated drug" includes a dangerous drug to which any of the following applies:

(1) A compounded dangerous drug if it exceeds the assigned beyond-use date.

(2) Meets any of the requirements described in section 3715.63 of the Revised Code.

(3) Is beyond the expiration date as stated by the manufacturer, repackager, or distributor in its labeling. This does not apply to expired drugs that are donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

(4) Is not stored, dispensed or personally furnished according to the requirement of the federal act as indicated in the product labeling.

(F) "Board of pharmacy" or "board" means the state board of pharmacy established under Chapter 4729. of the Revised Code.

(G) "Broker" means any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs in or into Ohio who does not take physical possession of the dangerous drugs. A broker shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a broker classification.

(H) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(I) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(J) "Disciplinary action," unless otherwise stated in this division, means any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:

(1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration, or certification;

(2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;

(3) An administrative fine or money penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand or probation;

(4) An action to reprimand or place the license, registration, or certification holder on probation;

(5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation or surrender;

(6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;

(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;

(8) The surrender or other relinquishment of a license, registration or certification in lieu of a formal sanction against a person's license, registration, or certificate, whether permanent or temporary;

(9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license, registration, or certification in the future;

(10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.

(K) "Manufacturer of dangerous drugs" or "manufacturer" means a person, other than a pharmacist or prescriber, that meets the following criteria:

(1) Meets the definition of a manufacturer pursuant in section 21 U.S. Code Section 360 eee (11/27/2013); and

(2) Manufactures dangerous drugs and who is engaged in the sale or distribution of dangerous drugs in or into Ohio.

(L) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.

(M) "Person" has the same meaning as in division (S) of section 4729.01 of the Revised Code and includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company or corporation.

(N) "Place on probation" means to take action against a license, for a period of time determined by the board, which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee may engage.

(O)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) **~~A method of positive identification relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.~~** **A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier.**

(P) "Readily retrievable" means that records maintained in accordance with this division shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.

(Q) "Refuse to grant or renew" means to deny original or continued licensure for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed by the board or a person seeking to attain such status by licensure, and whose license the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure, whose license the state board of pharmacy has refused to grant or renew, must meet all requirements established by the board in rule and as may be set forth in the person's board order.

(R) "Repackager of dangerous drugs" or "repackager" means a person that meets the following:

(1) Repacks and relabels dangerous drugs for sale or distribution; and

(2) Is required to register with the United States food and drug administration to engage in the repackaging or relabeling of dangerous drugs.

(S) "Reverse distribute" or "reverse distribution" means to acquire dangerous drugs for the purpose of any of the following:

(1) Return to a manufacturer or entity authorized by the manufacturer to accept returns on the manufacturer's behalf; or

(2) Destruction or disposal.

(T) "Revoke" means to take action against a license rendering such license void and such license shall not be reissued. Revoke is an action that is permanent against the licensee.

(U) "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

The shipment of dangerous drugs to a reverse distributor in this state licensed as a wholesale distributor of dangerous drugs in accordance with section 4729.52 of the Revised Code for the sole purpose of destruction or disposal of dangerous drugs, does not constitute a sale and does not require the person, if located outside of the state of Ohio, shipping the dangerous drugs to the reverse distributor to possess an Ohio license in accordance with Chapter 4729. of the Revised Code.

(V) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

(W) "Suspend" means to take action against a license rendering such license without force and effect for a period of time as determined by the state board of pharmacy. The board may require that an individual whose license or registration has been suspended may not be employed by or work in a facility licensed by the state board of pharmacy to possess or distribute dangerous drugs during such period of suspension.

(X) "Summary suspension" means to take immediate action against a license without a prior hearing rendering such license without force and effect for a period of time as indicated in section 4729.561 of the Revised Code. The board may suspend a license issued pursuant to Chapter 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(Y) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

(Z) "Virtual wholesaler" or "virtual wholesaler distributor" means any person engaged in wholesale distribution of dangerous drugs in or into Ohio who has title but does not take physical possession of the dangerous drugs. A virtual wholesale distributor shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a virtual wholesale distributor classification.

(AA) "Wholesale distributor of dangerous drugs" or "wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale or the reverse distribution of dangerous drugs and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

(BB) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

Rule 4729-3-01 | Disqualifying offenses. (AMEND)

(A) As used in ~~**agency**~~ **Chapter** 4729 of the Administrative Code, "disqualifying offense" means a criminal offense that is contained in the list adopted pursuant to paragraph (B) of this rule, and any existing or former criminal offense that is substantially equivalent to those explicitly contained in the list under municipal ordinances or laws of this state, any other state, or the United States, as required by division (B) of section 9.79 of the Revised Code.

(B) The board of pharmacy shall issue a resolution providing the list of specific criminal offenses for which a conviction, judicial finding of guilt, or plea of guilty may disqualify an individual from obtaining an initial license or registration issued by the board.

(C) The resolution shall be updated as necessary and shall be made available on the board's web site (www.pharmacy.ohio.gov).

(D) For the purposes of enforcing ~~**agency**~~ **Chapter** 4729**.** ~~**and 3796**~~ of the Administrative Code, a certified copy of a plea of guilty to, or a judicial finding of guilt of any crime in a court of competent jurisdiction is conclusive proof of the commission of all of the elements of that crime.

Rule 4729-5-01 | Recognized and approved schools of pharmacy. (AMEND)

(A) Pursuant to section 4729.08 of the Revised Code, the state board of pharmacy recognizes and approves all pharmacy programs or schools of pharmacy that have candidate or accreditation status with the accreditation council for pharmacy education (A.C.P.E.). The board, by resolution, reserves the right to:

(1) Deny the recognition or approval of a pharmacy program or school of pharmacy that meets A.C.P.E. candidate or accreditation status; or

(2) Recognize or approve a pharmacy program or school of pharmacy that does not meet A.C.P.E. candidate or accreditation status.

(B) For the purpose of satisfying the requirements of division (C) of section 4729.08 of the Revised Code, graduates of a school of pharmacy located outside the United States shall establish educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination ~~**Commission**~~ **Committee** (FPGEC)" certificate, and by establishing proficiency in spoken English by obtaining the minimum scores required by rule 4729:1-2-04 of the Administrative Code on the "Test of English as a Foreign Language, Internet-based test (TOEFL iBT)."

(C) The term "United States," as used in paragraph (B) of this rule, shall be deemed to include all states of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

Comments for Rule 4729:5-3-25 | Electronic product verification. (NEW)

Organization	Comment	Draft Response
National Association of Chain Drug Stores	On behalf of our members operating chain pharmacies throughout the state of Ohio, the Ohio Council of Retail Merchants (OCRM) and the National Association of Chain Drug Stores (NACDS) appreciate the opportunity to submit comments for consideration during the Common Sense Initiative review of the proposed new rule under OAC 4729:5-3-25 that authorizes electronic product verification. OCRM and NACDS are broadly supportive of the allowances authorized in this rulemaking that would allow pharmacists to use technology to complete the final product verification of finished prescriptions. Policies like this enable pharmacies to deploy flexible and innovative workflow models that bolster their capacity to deliver essential pharmacy care services to the public. However, we encourage the Board to make further revisions to the rulemaking to provide clarity and allow for practical flexibilities that preserve patient safety while aligning with real-world pharmacy operations – consistent with the direction to state agencies under the Common Sense Initiative to "promote […] flexibility while developing regulations." Specifically,	

	OCRM and NACDS recommend the following additional revisions to the proposed language under OAC 4729:5-3-25. 1. **Strike (B)(2) to allow out-of-state pharmacists to engage in remote prescription dispensing and do not restrict this activity to a pharmacist physically practicing in a pharmacy located in the state.** This change will afford Ohio pharmacies the added flexibility to utilize this technology in serving their patients by leveraging additional pharmacist capacity to perform activities. ~~(2) Physically practice in a pharmacy licensed as a terminal distributor of dangerous drugs that is located in this state where the electronic product verification is being conducted;~~ 2. **Amend (C)(1) to permit manual entry of lot and expiration date when 2D barcodes cannot be scanned due to damaged or missing barcodes.** This clarification will provide pharmacies with	Electronic product verification is a new technology that represents a significant shift from traditional pharmacy practice. As the Board is rolling out this technology, it needs to ensure that it can accurately address any issues that may negatively impact quality patient care. Therefore, having these activities performed in the state, in state licensed pharmacies, is essential to ensuring the Board can effectively regulate electronic product verification. Therefore, the Board did not make this amendment to the proposed rule. The barcode is there for product identification. If the barcode is damaged, the pharmacy cannot identify the drug. If the 2D barcode is damaged, it must be manually reviewed pharmacist.

	needed flexibility to manually enter lot number and expiration data in limited situations while maintaining patient safety. (1) The system shall use barcoding technology to ensure the accuracy of prescriptions or orders verified in accordance with this rule. Barcodes shall be scanned, and not manually typed, into the system**, except when 2D barcodes are damaged or unavailable. If 2D barcodes are damaged or missing, manual entry of lot and expiration data is permissible utilizing established policies and procedures.**	The lot number and expiration date can be captured using an image. This allowance was added to the rule in paragraph (C)(4)(e).
	3. Amend (C)(2) to clarify image resolution standards. Requiring every image to meet 300 pixels per inch may be impractical due to system limitations and variability in image capture. (2) The system shall ~~produce~~ **be capable of producing** images that are high definition with **sufficient** image resolution ~~of at least 300 pixels per inch~~ **to verify the prescription**.	These are the same image standards required for remote dispensing pharmacies. In the interest of consistency across the Board's remote practice rules, the Board proposes to keep this requirement. Commenters did not provide sufficient evidence of an unreasonable cost deviating from the standard established by the Board. Furthermore, the use of sufficient allows for significant variability. With no viable alternative language, the

		Board maintains the current language provides the most consistency.
	4. Strike (C)(4)(b) to eliminate the proposed requirement for electronic verification systems to include an image for pharmacists to verify the full quantity of the filled prescription. Displaying the full quantity of medications in filled prescription bottles is often not feasible (for example, sealed manufacturer containers) and exceeds what is reasonably necessary for final verification. Accuracy and patient safety are ensured through barcode scanning and established quality assurance processes. ~~(b) The full quantity of the filled prescription.~~	This provision is a requirement for remote verification under OAC 4729:5-18-05. As stated previously, the Board seeks to maintain consistency across all remote verification systems. Furthermore, this provision is included because it affords the pharmacist the same opportunity for visual inspection prior to verification. The Board contends that barcode scanning is one component to ensure accuracy, but that visual confirmation provides an additional level of assurance. The Board also believes that an image of the manufacturer container is important. Without it, the pharmacist cannot visually verify the product as they would normally do if conducting in-person product verification.
	5. Amend (C)(7) to reduce the retention period from one year to six months. Requiring	This provision is a requirement for remote verification under OAC 4729:5-18-05. As stated

	images to be retained for one year and embedded within the patient's profile create significant operational and storage burdens without a corresponding patient safety benefit. Many current electronic verification systems store images in secure, retrievable repositories rather than embedding them in the patient profile. Mandating that images be embedded into the profile would require unnecessary system redesign and added cost. Additionally, most verification-related reviews occur shortly after dispensing. (7) Images associated with the verification and dispensing of a prescription or order shall be retained in a secure and retrievable format and maintained for ~~one year~~ **six months** from the date of verification.	previously, the Board seeks to maintain consistency across all remote verification systems. As such, it believes the one-year retention is necessary. This allows for the preservation of records that may be involved in errors in dispensing or another quality assurance issue that must be investigated by the Board. The Board did modify the rule to remove the requirement that the images be maintained as part of the patient profile. Rather, the rule has been updated to require images to be in secure, uniform, and electronic format that is readily retrievable.
	6. Amend (H) addressing requirements for ongoing compliance with Ohio laws by clarifying that pharmacies must document (rather than "validate" and "revalidate")	Added definition of validation to clarify what is expected. Changed cadence for validation to an annual requirement and when there are new processes or material system changes.

	compliance with applicable Ohio laws and Board rules. Align the frequency of this documentation to at least annually and upon the addition of new processes. "Validated" is an undefined term, whereas documentation is well understood. Shifting the cadence of this requirement to an annual or as needed activity is more practical while still maintaining patient safety. (H) An electronic verification system shall be implemented and ~~validated~~ **documented** by an Ohio-licensed pharmacist prior to initial use to ~~ensure proper functioning~~ **confirm compliance with Ohio law and Board rules**. The system shall be ~~revalidated~~ **re-documented** by an Ohio-licensed pharmacist ~~in accordance with the pharmacy's policies and procedures at least once every six months~~ **at least annually, and upon the addition of new processes or material system changes, in accordance with the pharmacy's policies and procedures.** Altogether, we believe these targeted revisions maintain strong patient	

	safety controls while clarifying expectations and supporting practical, modern pharmacy operations. We welcome the opportunity to work with the Board and staff on implementation details, including policy templates and audit-ready documentation standards. OCRM and NACDS thank the Board for the opportunity to share our perspectives on this rulemaking. If you have any questions or need additional information, please contact OCRM's Lora Miller at loram@ohioretailmerchants.com or NACDS' Jill McCormack at JMcCormack@nacds.org.	
CVS Health	I am writing in my capacity as Executive Director of Board of Pharmacy Advocacy and Regulatory Affairs for CVS Health and its family of pharmacies. We appreciate the Ohio Board of Pharmacy ("Board") publishing a proposed *Electronic Product Verification Rule: 4729:5-3-25*. CVS Health previously submitted a letter of support during the initial comment period, which included proposed rule language that would have permitted remote electronic product verification. However, amendment to the language in Subsection (B) and the deletion of Subsection (L) have introduced ambiguity that could result in	The Board addressed this comment by permitting electronic product verification to be conducted in any Ohio pharmacy that is owned or operated by another pharmacy. It also amended the rule to permit the use of contract employees.

	inconsistent interpretations regarding the permissibility of remote electronic product verification, which were not addressed in the published input provided by the stakeholders in the business impact analysis. Accordingly, we respectfully request clarification and appropriate amendments during this second comment period. Image-based verification is widely utilized across community pharmacies, health systems, and multi-site pharmacy operations to support accuracy, promote workload balancing, and enhance safe dispensing. CVS Health recommends clarifying that the rule clearly states that it applies to remote electronic product verification performed through shared services, in which a pharmacist conducts final verification using image-based technology from a location other than where the prescription or medication order is being physically prepared. CVS Health respectively requests that the proposed rule 4729:5-3-25 be modified to expressly permit electronic product verification to be shared among pharmacies within Ohio. To address potential concerns, we offer the following proposed language, which includes reasonable limitations on such sharing:	

	(B) For a pharmacist to engage in electronic product verification, the pharmacist shall: (1) Be licensed as a pharmacist in this state; (2) Physically practice in a pharmacy licensed as a terminal distributor of dangerous drugs that is located in this state where the electronic product verification is being conducted; If the electronic product verification is performed by a remote pharmacy, on behalf of a pharmacy licensed as a terminal distributor of dangerous drugs that is located in this state, in compliance with OAC 4729:5-5-20, the pharmacy's policies and procedures shall impose reasonable limits on the number of remote pharmacies that may perform electronic product verification on behalf of a pharmacy licensed as a terminal distributor of dangerous drugs, which may be limited to 20% of the total pharmacy locations under common ownership within the state, not to exceed 50 locations. (a)The Board's executive director, or the director's designee, may waive the limitation on the number of remote pharmacies that may perform	

	electronic product verification on behalf of a pharmacy licensed as a terminal distributor of dangerous drugs. (b) If a state of emergency is declared, the number of remote pharmacies that may perform electronic product verification on behalf of a pharmacy licensed as a terminal distributor of dangerous drugs may be temporarily expanded without Board approval until such time as the state of emergency is resolved. (3) Complete the required training and competency evaluations in paragraph (G) of this rule; and (4) Be a current or contracted employee of the pharmacy or pharmacies under common ownership, operating, using, or making use of the electronic verification system. CVS Health appreciates the Board's leadership in advancing modern pharmacy practice while maintaining a strong focus on patient safety. Thank you for your consideration of these comments and for amending the proposed rule to expressly permit remote electronic product verification through shared services.	

Rule 4729:5-3-25 | Electronic product verification. (NEW)

(A) As used in this rule:

(1) "Electronic product verification" or “electronic verification” means the non-physical dispensation (“final check”) of a drug or device by a pharmacist using an electronic verification system to verify the accuracy of the drug or device and affixed label prior to dispensing. Electronic final verification does not include the following:

(a) Operation of a remote dispensing pharmacy pursuant to Chapter 4729:5-18 of the Administrative Code;

(b) The practice of remote outpatient prescription processing pursuant to rule 4729:5-5-20 of the Administrative Code;

(c) The practice of remote medication order processing pursuant to rule 4729:5-9-02.14 of the Administrative Code;

(d) The practice of personally furnishing by a prescriber pursuant to division 4729:5 of the Administrative Code; or

(e) The dispensation of a drug or device from an automated pharmacy system pursuant to rule 4729:5-3-17 of the Administrative Code.

(2) “Electronic verification system” means a system that complies with the requirements set forth in this rule.

(B) For a pharmacist to engage in electronic product verification, the pharmacist shall:

(1) Be licensed as a pharmacist in this state.

(2) Physically practice in a pharmacy licensed as a terminal distributor of dangerous drugs that is:

(a) Located in this state; and

(b) Under the same common ownership and control.

(3) Complete the required training and competency evaluations in paragraph (G) of this rule.

(4) Is a current or contracted employee of the pharmacy operating the electronic verification system.

(C) An electronic verification system shall allow the pharmacist to see an exact, clear, and unobstructed visual images of the drug or device being dispensed and the label affixed to the container. The system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a drug or device and sufficient data retention capabilities to investigate any quality-related events.

(1) The system shall use barcoding technology to ensure the accuracy of drugs or devices dispensed in accordance with this rule. Barcodes shall be scanned, and not manually typed, into the system. The board may waive or modify the barcode technology requirements listed in this paragraph if the electronic verification system can provide an alternative method to ensure the accuracy of drugs or devices dispensed in accordance with this rule.

(2) The system shall produce images that are high definition with image resolution of at least 300 pixels per inch and in full color.

(3) If multiple units are being dispensed, the pharmacist must be able to see and verify an image or images of each unit and each individual affixed label.

(4) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing.

(a) A clear image of the prescription label affixed to the drug or device;

(b) The full quantity of the filled prescription;

(c) Except as provided in paragraph (C)(5) of this rule, the medication stock bottle or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code used to fill the prescription, if applicable; and

(d) Clear markings present on the drug being dispensed (e.g., tablets, capsules, etc.)), if applicable.

(e) A clear image of the following, if not otherwise captured or maintained in the pharmacy system:

(i) The drug's national drug code, as defined in 21 CFR 207.33 (April 1, 2026), or global trade item number; and

(ii) The drug's serial number, lot number, and expiration date.

(5) The board may waive or modify the requirements listed in paragraph (C)(4)(c) of this rule if the electronic verification system can provide an alternative method that accurately captures information from the medication stock bottle and/or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(6) The system shall use stock images of the correct drug, including markings if applicable.

(7) Images associated with the electronic product verification shall be retained in a secure, uniform, and electronic format and maintained for one year from the date of verification. Images associated with electronic product verification shall be made readily retrievable.

(8) Use of an electronic verification system shall be terminated if the system is not properly functioning. Prior to resuming the use of the system, the pharmacy shall identify the root cause or causes of the malfunction and shall validate that the system is properly functioning.

(9) The electronic verification system shall be capable of clearly communicating that the pharmacist has verified the drug or device prior to sale or distribution.

(10) Prior to dispensing, a pharmacist shall review and authorize overrides performed by a pharmacy technician or pharmacy intern of any technologically generated errors, warnings, alerts, or exceptions related to system functionality or verification/accuracy. Documentation of the pharmacist's review and authorization must be captured using electronic positive identification and maintained for three years from the date of review in a readily retrievable format.

(11) A pharmacist shall not be required to conduct electronic product verification if, in the pharmacist's professional judgement, the system, personnel, or processes employed by the pharmacy present a danger to the health and safety of patients.

(D) All electronic product verification shall be documented using an electronic form of positive identification in accordance with rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.

(E) No further manipulation of a drug or device shall occur after the pharmacist's electronic verification is complete other than applying the required container lid or seal. Manipulation does not include preparing a finished prescription/medication order for mailing, sale, delivery, or storage.

(F) Except as provided for in this paragraph, a pharmacist shall not conduct electronic product verification of compounded drug preparations. A pharmacist may utilize electronic product verification as part of the compounding process as follows:

(1) The pharmacist complies with all applicable requirements of this rule.

(2) Only components used for compounded drug preparations may be verified by a pharmacist using an electronic verification system.

(3) Reconstituted drug products (ex. stock solutions) may be used or manipulated for compounding after the pharmacist's electronic verification is complete.

(4) At the completion of the compounding process and prior to release or dispensation, sale, or distribution, the compounded drug preparation shall be visually inspected by a pharmacist in person to determine whether the physical appearance of the drug is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects) and that the container closure integrity is in compliance with all applicable United States Pharmacopeia chapters referenced in rule 4729:7-1-01 of the Administrative Code. A pharmacist shall document this verification using positive identification.

(G) All pharmacy personnel utilizing electronic final verification system must be trained and competent to perform the duties assigned and have a documented initial and annual assessment of competency using the pharmacy's electronic verification system.

(H) An electronic verification system shall be implemented and validated by an Ohio-licensed pharmacist prior to initial use to ensure proper functioning. The system shall be validated by

an Ohio-licensed pharmacist in accordance with the pharmacy's policies and procedures at least annually, and upon the addition of new processes or material system changes.

(1) Validation is a documented process established by the terminal distributor of dangerous drugs that proves the electronic verification system consistently operates according to its intended use, specifications, and requirements of this rule.

(2) Proof of compliance with validation requirements shall be documented by an Ohio-licensed pharmacist and maintained in a readily retrievable format for three years from the date of validation or revalidation.

(3) The records shall document the positive identification of the pharmacist performing the required validation, date(s) performed, and the results of the validation.

(I) Pharmacies using an electronic verification system as authorized by this rule shall maintain an ongoing and documented quality assurance system that monitors the performance of the electronic verification system to ensure proper and accurate functioning in accordance with rule 4729:5-3-22 of the Administrative Code. The quality assurance system shall also include procedures for reporting system malfunctions.

(J) Pharmacies utilizing an electronic verification system pursuant to this rule shall maintain and implement written policies and procedures governing all aspects of electronic verification activities. Such policies and procedures shall be maintained in a readily retrievable format and shall include, but are not limited to, the following:

(1) Staff training and competency assessments;

(2) Operation of the quality assurance system, including reporting, investigating and addressing errors, system malfunctions, and other quality assurance issues;

(3) Validation and revalidation of electronic verification technology to ensure proper functioning; and

(4) System maintenance, including any routine or preventive maintenance.

(K) Pharmacies using an electronic verification system shall comply with all applicable record keeping requirements pursuant to rule 4729:5-5-04 or rule 4729:5-9-02.3 of the Administrative Code.

(L) A pharmacy licensed as a terminal distributor of dangerous drugs that is engaged in electronic product verification shall comply with all minimum standards for the operation of a pharmacy including rule 4729:5-5-02 of the Administrative Code and all supplemental rules adopted thereunder.

Comments for Rules 4729:5-4-01 & 4729:6-4-01 – Disciplinary actions.

Name	Organization	Comment
Lee Ann Werner	Ode Ventures	Ode Ventures provides capital, business coaching and marketing expertise to aspiring entrepreneurs so that they may achieve their business goals. We serve a variety of industries including health & wellness, professional services, recreation, construction, and the non-profit sector. We are writing in response to the Ohio Board of Pharmacy's (the "Board") Winter 2025-2026 Rules for Stakeholder Comment issued December 8, 2025. The proposed changes to Rule 4729:5-4-01 extends the list of sanctionable actions by TDDD licensees. For example, Rule 4729:5-4-01(B)(26)(l) suggests that a TDDD licensee operating as a corporation or limited liability company will be restricted in the shareholders or members it may conduct business with. Specifically, the Board seeks to prevent a TDDD licensee from associating with a shareholder or member that "has participated in ***any capacity*** in the operation or ownership of an entity licensed by the [B]oard….that has been suspended, revoked, or disciplined by the [B]oard for violations of section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925, 3715, 3719, 4729 of the Revised Code, or any rule of the [B]oard." We request that the Board consider revising Rule 4279:5-4-01(B)(26)(l) to instead prevent TDDD licensees from working with shareholders or members who had an ***active*** role in the operation of an entity licensed by the Board that was subject to suspension, revocation or discipline. Alternatively, we ask that the Board explicitly carve out passive investors from this rule to make clear that they are not prevented from working with other TDDD licensees in the future should a previous

		venture with a TDDD licensee result in Board suspension, revocation, or discipline, unrelated to the investor's involvement with such licensee. We appreciate the Board's commitment to pursue optimal standards of practice. As Ode Ventures continues to grow its involvement in the health & wellness industry, we respectfully request the Board consider our comments to Rule 4729:5-4-01(B)(26)(l).
Sean McCullough	Ohio Dermatological Association	The Ohio Dermatological Association (ODA) appreciates the opportunity to submit stakeholder comments on the Board's proposed Winter 2025–2026 rule package. While the package includes several miscellaneous amendments, ODA's comments are limited to proposed changes to Rule 4729:5-4-01 governing disciplinary actions applicable to terminal distributors of dangerous drugs (TDDD). This rule is of particular importance to our physician members who hold TDDD licenses in connection with their medical practices. ODA has significant concerns regarding the proposed amendments to paragraph (B)(26) of Rule 4729:5-4-01. Under the current rule, disciplinary exposure is tied to a terminal distributor knowingly employing a person *with access to drug stock* who has engaged in specified disqualifying conduct. The proposed amendments appear to remove the "access to drug stock" limitation and substantially expand the scope of relationships that may subject a TDDD licensee to discipline. As proposed, a terminal distributor may face disciplinary action not only for employing such an individual, but also for knowingly contracting with, or having any agent, owner, partner, member, officer, director, or manager, or in the case of corporate entities, certain direct or indirect owners, who has engaged in the listed conduct.

		From ODA's perspective, this represents a significant shift in regulatory policy and a material expansion of the universe of individuals whose conduct may expose a physician-held TDDD license to discipline. The proposed language appears to move beyond individuals with operational or physical access to dangerous drugs and instead sweep in a broad range of relationships that may have little or no connection to drug handling, storage, or dispensing activities. As written, the scope of potential exposure is unclear and potentially far-reaching. ODA is also concerned by the lack of clarity regarding how these provisions would be interpreted and enforced in practice. For example, the proposed rule does not explain what standards the Board would apply to determine whether a licensee "knowingly" employed, contracted with, or maintained a relationship with an individual who meets one of the listed criteria. Nor is it clear what, if any, due diligence or monitoring obligations the Board expects TDDD licensees, many of whom are physicians operating medical offices, to undertake with respect to employees, contractors, corporate stakeholders, or affiliated individuals. Without additional guidance, it is difficult for licensees to understand how compliance could reasonably be achieved. Additionally, ODA has questions regarding the rationale for this policy change. It is not apparent from the proposed rule or accompanying materials what enforcement issues or regulatory gaps prompted such a seemingly broad expansion of disciplinary exposure for terminal distributors, particularly those operated by physicians. TDDD licensed physicians are already subject to extensive regulation through their professional licensure and are among the most highly trained and regulated professionals in the

		healthcare system. ODA is concerned that the proposed amendments may impose new and ill-defined obligations on physician practices without a clear nexus to patient safety or drug diversion risks. For these reasons, ODA respectfully requests additional clarification from the Board regarding the intent, scope, and anticipated application of the proposed amendments to Rule 4729:5-4-01. At a minimum, ODA believes further stakeholder discussion is warranted before such a substantial expansion of disciplinary exposure is adopted. We would welcome the opportunity to engage with the Board to better understand the policy objectives underlying these changes and to discuss potential refinements that provide clarity and proportionality for physician-operated terminal distributors. Thank you for your consideration of these comments and we look forward to discussing further.
Nick Meza	Quarles	We write on behalf of multiple stakeholders holding terminal distributor of dangerous drugs and drug distributor licenses in Ohio. We appreciate the opportunity to submit comments on the Board's proposed amendments to select rules as part of the Winter 2025–2026 rulemaking process, and we acknowledge the Board's ongoing efforts to protect public health, ensure drug security, and maintain the integrity of the regulated supply chain. Within the final two pages of this letter, we provide alternative language for the Board's consideration. These comments focus on the proposed revisions to Rules 4729:5-4-01 and 4729:6-4-01, governing disciplinary actions for terminal distributors and drug distributors. Taken together, the amendments would significantly alter the existing disciplinary framework by expanding liability beyond employment relationships tied to access to drug stock, extending discipline to contracting relationships and passive

		ownership interests, and imposing new ownership-transfer restrictions untethered from post-transfer control or operational influence. As drafted, the proposals would also materially restrict the ability to purchase, sell, or invest in licensed facilities, including through legitimate remediation-focused acquisitions. While we recognize the Board's statutory authority to regulate distributor ownership and to discipline licensees that knowingly employ individuals who pose a risk to drug security or patient safety, that authority has historically been exercised in a manner grounded in operational control, access to dangerous drugs, and conduct connected to regulated activities. The proposed amendments depart from this risk-based approach by extending disciplinary exposure to relationships and associations that may bear no connection to facility operations, drug handling, or compliance oversight. In doing so, the amendments raise serious concerns regarding proportionality, administrability, predictability, and alignment with established principles of licensure accountability. **I. The Revised Ownership-Transfer Provision Expands the Board's Disciplinary Authority Beyond Its Intended Purpose** The proposed amendments to the ownership-transfer provisions applicable to terminal distributors of dangerous drugs and drug distributors (Rules 4729:5-4-01(A)(21) and 4729:5-4-01(A)(23)) fundamentally alter the purpose of the existing rule. The prior framework appropriately targeted situations where a former owner whose license had been revoked or disciplined continued to exert influence over a facility following a purported sale. That approach focused on

		preventing sham transactions designed to evade enforcement, while allowing legitimate buyers to acquire and remediate troubled facilities. The proposed amendments state: (A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a**n applicant or** person licensed as a terminal distributor of dangerous drugs [or distributor of dangerous drugs] for any of the causes set forth in paragraph (B) of this rule: ******* (21) [23] The ownership of such facility has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other [or federal] professional licensing agency to another who employs **or contracts with** the former owner **or the spouse, family member, or previous employee or agent of the person whose license was revoked or disciplined.** ~~or who allows the former owner to be present within the physical confines of the location to be licensed.~~ The revised provisions depart from this principle by presuming bad faith based on relationship alone. As drafted, the rule would permit discipline where ownership is transferred to a new licensee who employs or contracts with not only the former owner, but also the former owner's spouse, family member, or any prior employee or agent, without any requirement that the former owner retain control, influence, or involvement in licensed operations. In effect, the rule assumes circumvention whenever a transfer involves individuals with any prior association to the

		disciplined owner, regardless of the circumstances of the transaction or the absence of ongoing control. It would also allow the Board to discipline an *applicant*, apparently regardless of whether or not a permit is issued, essentially allowing the Board to discipline an individual or entity before any violation occurred at a regulated facility. This approach shifts the focus away from the only concern that justifies post-transfer discipline: whether the former owner continues to maintain control or operational influence over the facility after the transfer. Where the former owner is fully divested, removed from decision-making, and excluded from licensed operations, the presence of other individuals with historical or personal relationships to that owner does not, by itself, present a risk to compliance or patient safety. By treating association as a proxy for misconduct, the revised rule risks penalizing good-faith purchasers, including publicly traded companies and other sophisticated operators that routinely acquire distressed assets to improve compliance, governance, and operational performance. These entities often retain existing personnel or engage individuals with historical ties to prior ownership to ensure continuity of care and operational stability, not to perpetuate improper control. Subjecting such transactions to disciplinary risk discourages remediation-focused acquisitions and undermines the regulatory objective of improving compliance outcomes. Absent a requirement that the former owner retain control or exercise influence post-transfer, the revised ownership-transfer provision is overinclusive and misaligned with its intended purpose. A more narrowly tailored approach focused on actual control, decision-making authority, or intentional circumvention would better protect the public while avoiding unnecessary harm to lawful transactions and good-actor purchasers.

		II. The Proposed Amendments to 4729:5-4-0 and 4729:5-4-01 Abandon a Risk-Based Disciplinary Framework Tied to Operations Under existing Rules 4729:5-4-01(A)(26) and 4729:5-4-01(A)(24), disciplinary authority is appropriately tied to a license holder's knowing employment of individuals with access to drug stock who meet specified disqualifying criteria. This framework reflects a clear nexus between an individual's role, access to dangerous drugs, and the licensee's responsibility to safeguard the drug supply. However, the Board has proposed revisions that depart from this framework and unnecessarily expand the scope of the relationships which may give rise to disciplinary action. The revisions to the terminal distributor section [which mirror the drug distributor section] state: (A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a**n applicant or** person licensed as a terminal distributor of dangerous drugs [or distributor of dangerous drugs] for any of the causes set forth in paragraph (B) of this rule: *** * *** (26)[24] Unless otherwise approved by the board, a terminal distributor knowingly**:** employs **or contracts with** a person**; has any agent, owner, partner, member, officer, director or manager of the applicant or person licensed as a terminal distributor of dangerous drugs; or if the applicant or licensee is a corporation or limited liability company, any shareholder directly or indirectly owning**

		voting interests or membership interests in the corporation or limited liability company, who: ~~with access to drug stock who~~**:** *** * *** **(l)[m] Has participated in any capacity in the operation or ownership of an entity licensed by the board that has demonstrated a disregard for the laws or regulations of this state or any other state, including but not limited to, an entity that has been suspended, revoked, or disciplined by the board for violations of section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., 4729. of the Revised Code, or any rule of the board.** As drafted, the proposal no longer limits disciplinary exposure to employees with access to drug stock. Instead, it extends liability to a broad and undefined set of relationships, including contractors, agents, owners, managers, and shareholders, without regard to whether those individuals have access to drugs, exercise operational control, or are involved in regulated activities at all, and even in situations where an application was submitted but not granted. This expansion has several significant consequences summarized below. **a. The Proposal Improperly Restricts Ordinary Contracting Relationships** By expanding the rule from "employs" to "employs or contracts with," the proposal would materially restrict a licensee's ability to engage in ordinary and necessary commercial relationships with unaffiliated third parties. As

		drafted, a terminal or drug distributor could face disciplinary action merely for contracting with an IT vendor, consultant, or service provider if the licensee knows that the individual has engaged in one of the listed acts, regardless of whether that individual's role bears any connection to drug handling, compliance functions, or patient safety. This expansion eliminates the limited nature of the existing rule, which appropriately ties discipline to employment relationships involving *access to drug stock*. In contrast, contracting relationships often involve discrete, arm's-length services performed by individuals who do not enter licensed facilities, do not handle dangerous drugs, and do not exercise any control over regulated operations. Subjecting such relationships to disciplinary scrutiny unlawfully restricts freedom of contract, conflates ordinary business arrangements with pharmacy practice, and extends the Board's authority well beyond its mission to protect the public health. Moreover, the breadth of the disqualifying criteria compounds this concern. The proposal would permit discipline based on personal history or status, including substance-use issues or prior legal outcomes, without any requirement that the conduct be related to the services provided or to regulated activities. In practical effect, licensees would be forced to screen, monitor, and potentially exclude a wide range of third-party vendors and professionals based on considerations unrelated to drug security, or else risk discipline of the license itself. This outcome is neither administrable nor consistent with a risk-based regulatory framework focused on safeguarding the drug supply.

		b. Extending Discipline to Shareholders Creates an Unworkable Standard The proposed inclusion of "any shareholder directly or indirectly owning voting interests or membership interests" raises particularly serious concerns because it untethers disciplinary exposure from any meaningful concept of control, influence, or involvement in regulated activities. Ownership interests, standing alone, do not equate to participation in pharmacy operations, access to drug stock, or responsibility for compliance with the Board's rules. For publicly traded entities, this language could encompass thousands, or even millions, of passive investors holding interests through public markets, mutual funds, retirement accounts, or other investment vehicles. These individuals have no operational role, no access to dangerous drugs, and no practical ability to influence day-to-day compliance decisions. Yet under the proposal, the mere existence of such shareholders could create disciplinary risk if a licensee is aware of a disqualifying fact related to any one of them, regardless of the size of the ownership interest or the shareholder's lack of involvement in licensed activities. The rule also fails to distinguish between controlling owners and de minimis investors, or between closely held entities and publicly traded companies. As a result, it imposes compliance obligations that no widely held entity could reasonably satisfy, including the ongoing monitoring of personal histories of vast and constantly changing shareholder populations. This lack of a limiting principle not only renders the provision unworkable in practice, but also risks discouraging lawful ownership structures and investment in licensed facilities without providing any corresponding benefit to patient safety or drug security.

		c. The Rule Imposes Association-Based Liability and Creates Regulatory Uncertainty By eliminating the access-to-drug-stock limitation and extending the rule to contractors, agents, and shareholders, the proposed rule seeks to impose discipline based on association rather than conduct. As drafted, a licensee could face sanctions absent any showing that the individual exercised control over regulated activities, had access to dangerous drugs, or engaged in misconduct connected to the licensed operations. Nor does the rule require that the licensee had a reasonable ability to prevent or remediate the issue. This departure from a nexus-based framework transforms the provision from a targeted safeguard into a form of strict or vicarious liability untethered from pharmacy operations. At the same time, the proposed amendments create substantial uncertainty regarding compliance and enforcement. The rule provides no guidance on the level of diligence required, how "knowledge" is established, or how a violation may be cured once identified. Faced with these ambiguities, regulated entities will be incentivized to over-exclude and avoid otherwise lawful relationships and ownership structures, even where no risk to the drug supply exists. This outcome would disproportionately impact larger, multi-state, and publicly held entities, while offering little corresponding benefit to patient safety or drug security. A more narrowly tailored approach would better serve the Board's public-health mission while preserving clarity, fairness, and enforceability. **d. The Addition of a Broad and Subjective Disqualification Standard Creates Enforcement Uncertainty**

		The proposed rule also introduces a new condition that may independently give rise to disciplinary action, significantly expanding the Board's enforcement authority beyond established and objective standards. Proposed subsections under 4729:5-4-01(A)(26)(l) and 4729:5-4-01(A)(24)(m) permit discipline where an individual has participated "in any capacity" in the ownership or operation of an entity that has "demonstrated a disregard for the laws or regulations of this state or any other state." This language is not tied to any defined level of culpability, control, or involvement, nor does it require a final adjudication, material violation, or finding of intentional misconduct. As drafted, the provision could sweep in individuals whose participation was limited, historical, or unrelated to the conduct giving rise to the underlying discipline, including minority owners, former officers, or individuals who exited an entity prior to any enforcement action. The standard also extends across jurisdictions and regulatory regimes, without specifying what constitutes a "disregard" for the law or how such a determination is to be made. The absence of objective criteria or limiting principles makes this provision difficult, if not impossible, to operationalize and grants the Board effectively unchecked discretion to impose discipline based on subjective assessments of past associations. Without clearer standards, licensees are left without meaningful notice of prohibited conduct or a workable path to compliance, raising significant concerns regarding fairness, predictability, and consistent enforcement. **III. Request for Reconsideration or Narrowing**

		For the reasons outlined above, we respectfully urge the Board to reconsider the breadth of the proposed amendments to Rules 4729:5-4-01 and 4729:6-4-01. While we support the Board's authority to protect the integrity of the drug supply and to prevent circumvention of disciplinary actions, the proposed revisions extend beyond those objectives and risk creating standards that are overbroad, difficult to administer, and disconnected from operational risk. We encourage the Board to consider the following targeted refinements, which are reflected in the attached draft. **a. Prohibited Ownership-Transfer Provisions** With respect to the ownership-transfer provisions, the rules should be narrowed to focus on the core concern they were originally designed to address: Whether a former owner whose license has been revoked or disciplined continues to exercise control or operational influence over a licensed facility following a transfer. Discipline should not be triggered solely by association with the former owner, including familial, professional, or historical relationships, absent evidence of continued control or intentional circumvention, or simply by filing an application that may include these relationships. A more targeted approach would preserve the Board's enforcement authority while allowing good-faith purchasers, including publicly traded and multi-state operators, to acquire and remediate facilities in a manner that improves compliance and protects patient safety. **b. Expanded Disciplinary Provisions** With respect to the expanded disciplinary provisions, the Board should restore a risk-based framework that limits disciplinary exposure to individuals whose roles involve

		operational control over regulated activities. At a minimum, we encourage the Board to: • Retain an employment-based framework limited to individuals with access to drug stock. • Remove or significantly narrow the application to contracting relationships. • Exclude passive shareholders and indirect ownership interests from the scope of the rule. • Limit applicability to individuals with operational control or direct involvement in regulated activities. • Clarify knowledge standards, diligence expectations, and available remediation options. • Expressly exclude publicly traded companies or, alternatively, limit the shareholder provisions to closely held entities where ownership interests confer actual control or influence over licensed operations. These principles are reflected in the attached draft revisions submitted for the Board's consideration. By narrowing the proposed amendments in this manner, the Board can advance its public-health mission while maintaining a regulatory framework that is clear, administrable, and appropriately focused on conduct that presents genuine risk to the drug supply. We appreciate the Board's consideration of these comments and the opportunity to participate in the rulemaking process. We respectfully submit that a more narrowly tailored approach, grounded in operational control, access to dangerous drugs, and intentional circumvention, would

		better serve the Board's public-health mission while avoiding unintended consequences for lawful transactions and good-faith operators. We stand ready to engage further with the Board as it evaluates potential revisions to the proposed rules.

Rule 4729:5-4-01 | Disciplinary actions. (AMEND)

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a**n applicant or** person licensed as a terminal distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

(1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;

(2) Reprimand or place the license holder on probation;

(3) Impose a monetary penalty or forfeiture as set forth in section 4729.57 of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

(1) Making any false material statements in an application for a license or renewal of a license as a terminal distributor of dangerous drugs.

(2) Violating any rule of the board.

(3) Violating any provision of Chapter 4729. of the Revised Code.

(4) Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code.

(5) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code.

(6) Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor.

(7) Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code.

(8) Except as provided in division (C) of section 4729.57 of the Revised Code:

(a) Waiving the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the services provided by a terminal distributor of dangerous drugs, would otherwise be required to pay for the services if the waiver is used as an enticement to a patient or group of patients to receive pharmacy services from that terminal distributor;

(b) Advertising that the terminal distributor will waive the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the pharmaceutical services, would otherwise be required to pay for the services.

(9) Conviction of a felony.

(10) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee.

(11) Exclusion from participation in medicare or a state health care program.

(12) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(13) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(14) Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(15) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(16) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(17) Is addicted to or abusing alcohol or drugs.

(18) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(19) Employs a responsible person that does not meet the requirements set forth in rule 4729:5-2-01 of the Administrative Code.

(20) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other professional licensing agency to a spouse**, ~~or other~~** family member**, or previous employee or agent of the person whose license was revoked or disciplined.**

(21) The ownership **of** such facility has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing agency to another who employs **or contracts with** the former owner **or the spouse, family member, or previous employee or agent of the person whose license was revoked or disciplined.** ~~**or who allows the former owner to be present within the physical confines of the location to be licensed.**~~

(22) Except as provided in Chapter 3719. of the Revised Code, dispensing a sample drug as defined in rule 4729:6-3-08 of the Administrative Code.

(23) The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(24) The furnishing of false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of dangerous drugs from manufacturers, repackagers, third-party logistics providers, outsourcing facilities, wholesale distributors or other terminal distributors.

(25) Retaliating against or disciplining an employee for filing a complaint with a board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

(a) Removing or suspending the employee from employment;

(b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(c) Transferring or reassigning the employee;

(d) Denying the employee a promotion that otherwise would have been received;

(e) Reducing the employee in pay or position.

(26) Unless otherwise approved by the board, a terminal distributor knowingly: employs **or contracts with** a person**; has any agent, owner, partner, member, officer, director or manager of the applicant or person licensed as a terminal distributor of dangerous drugs; or if the applicant or licensee is a corporation or limited liability company, any shareholder directly or indirectly owning voting interests or membership interests in the corporation or limited liability company, with access to drug stock or any role in the purchasing, ordering, directing, or recommending of drug stock who:** ~~**with access to drug stock who:**~~

(a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(c) Has committed an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(d) Has committed an act that constitutes a misdemeanor or felony drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(e) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(f) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(g) Is addicted to or abusing alcohol or drugs.

(h) Has been excluded from participation in medicare or a state health care program.

(i) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(j) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(k) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the ~~**employee's**~~ **individual's** professional practice.

(l) Has actively participated in the operation or ownership of an entity licensed by the board that has demonstrated a disregard for the laws or regulations of this state or any other state, including but not limited to, an entity that has been suspended, revoked, or disciplined by the board for violations of section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., 4729. of the Revised Code, or any rule of the board.

Rule 4729:6-4-01 | Disciplinary actions. (AMEND)

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a**n applicant or** person licensed as a distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

(1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;

(2) Reprimand or place the license holder on probation;

(3) Impose a monetary penalty or forfeiture as set forth in section 4729.56 of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

(1) Making any false material statements in an application for licensure or licensure renewal under section 4729.52 of the Revised Code.

(2) Violating any federal, state, or local drug law; any provision of Chapter 2925., 3715., 3719., or 4729. of the Revised Code; or any rule of the board.

(3) A conviction of a felony.

(4) Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(5) Failing to satisfy the qualifications for licensure under section 4729.53 of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the license is granted or renewed.

(6) Falsely or fraudulently promoting to the public a drug that is a controlled substance included in schedule I, II, III, IV, or V, except that nothing in this rule prohibits a drug distributor from furnishing information concerning a controlled substance to a health care provider or licensed terminal distributor.

(7) ~~**Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), United States Code Title 21 (10/22/2017).**~~ **Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301.**

(8) Failing to comply with the requirements of rule 4729:6-3-05 of the Administrative Code.

(9) Conducting the sale of a suspicious order without conducting an independent analysis prior to completing a sale to determine whether the reported drugs are likely to be diverted from legitimate channels in accordance with rule 4729:6-3-05 of the Administrative Code.

(10) Commission of a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(11) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee.

(12) Exclusion from participation in Medicare or a state health care program.

(13) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(14) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(15) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(16) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(17) Is addicted to or abusing alcohol or drugs.

(18) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(19) Employs a responsible person that does not meet the requirements set forth in rule 4729:6-2-01 of the Administrative Code.

(20) Retaliating against or disciplining an employee for filing a complaint with a board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

(a) Removing or suspending the employee from employment;

(b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(c) Transferring or reassigning the employee;

(d) Denying the employee a promotion that otherwise would have been received;

(e) Reducing the employee in pay or position.

(21) The method used by the drug distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(22) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to a spouse**, ~~or other~~** family member**, or previous employee or agent of the person whose license was revoked or disciplined**.

(23) The ownership **or right of access** ~~**of**~~ **to** such facility has been transferred from **the real property owner or** a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to another who employs **or contracts with** the former owner **or the spouse, family member, or previous employee or agent of the person whose license was revoked or disciplined.** ~~**or who allows the former owner to be present within the physical confines of the location to be licensed.**~~

(24) Unless otherwise approved by the board, a distributor knowingly: employs **or contracts with** a person**; has any agent, owner, partner, member, officer, director or manager of the applicant or person licensed as a distributor of dangerous drugs; or if the applicant or licensee is a corporation or limited liability company, any shareholder directly or indirectly owning voting interests or membership interests in the corporation or limited liability company, with access to drug stock or any role in the purchasing, ordering, directing, or recommending of drug stock who:** ~~**with access to drug stock who:**~~

(a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(c) Has committed an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(d) Has committed an act that constitutes a misdemeanor or felony drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(e) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(f) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(g) Is addicted to or abusing alcohol or drugs.

(h) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

(i) Has been excluded from participation in medicare or a state health care program.

(j) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(k) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(l) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the ~~**employee's**~~ **individual's** professional practice.

(m) Has actively participated in the operation or ownership of an entity licensed by the board that has demonstrated a disregard for the laws or regulations of this state or any other state, including but not limited to, an entity that has been suspended, revoked, or disciplined by the board for violations of section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., 4729. of the Revised Code, or any rule of the board.

Comments on Five Year Review Package (Outpatient Pharmacy, Pharmacy Technicians, Pharmacists, Drug Distributors)

Name	Organization	Comment	Draft Board Response
Sophia Brickley, MPH	University Hospitals	To Whom It May Concern, University Hospitals (UH) appreciates the opportunity to provide comments on the FYR TDDD rule package currently under CSI review. We value the Board's ongoing work to ensure safety in the distribution of dangerous drugs and appreciate the transparency and engagement throughout this process. Based on internal review and discussions with our outpatient and inpatient pharmacy leaders, UH offers the following comments, questions, and recommended modifications for clarification. **Rule 4729:5-4-02 – Duty to Report** *(Pharmacist refusal to dispense suspected fraudulent prescriptions)* Pharmacy leaders expressed concern that paragraph (B)(6), which requires reporting when	Pharmacists have a corresponding responsibility under the state and federal law to refuse to dispense a prescription that is of doubtful, questionable, or suspicious origin.

		a pharmacist refuses to dispense due to suspected fraud, appears primarily retail-focused and may unintentionally cause pharmacists to feel as though their professional judgment is being monitored. UH respectfully requests clarification on the intent of this reporting requirement: ▪ Is the reporting intended to support fraud detection and prevention, or ▪ Is the intent to track decisions made by individual pharmacists? Additional guidance would be helpful regarding what constitutes a "suspected fraudulent" prescription or order. Providing examples or criteria would assist pharmacies in applying this requirement consistently while also ensuring pharmacists do not fear punitive oversight for exercising clinical judgment.	With the advent of new technologies, the Board continues to see cases of fraud as it relates to the issuance of prescriptions. The intent of the rule is to require proactive reporting by the pharmacy and not the individual pharmacist. It is the expectation of the Board that existing procedures exist if/when a fraudulent prescription is identified. Therefore, it is an organizational requirement to report suspected fraud rather than on the individual pharmacist. To improve clarity the Board added a few examples to the rule text and will also issue additional guidance to assist licensees in complying with this rule. It will mirror existing guidance from DEA regarding fraudulent prescriptions https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-002R1)(EO-DEA009R1)_RPH_Guide_to_RX_Fraud_Trifold_(Final).pdf

			Furthermore, each licensee has its own Board assigned inspector. A licensee may contact their BOP assigned staff with any questions regarding potential fraud reporting.
		Rule 4729:5-4-02 – Duty to Report *(Receipt of an illegitimate product)* Our pharmacy teams identified no significant concerns with paragraph (B)(7), which adds receipt of an illegitimate product to the list of reportable events. The structure of the requirement is clear. UH simply requests confirmation that reporting is required only after coordination with the manufacturer, as described in paragraph (E)(4).	The Board expects a licensee to follow federal law and report to the Board when they also report to the FDA. Therefore, the language in the rule has been adjusted to reflect that the Board must be notified within 24 hours of notification to FDA.
		Rule 4729:5-4-02(E)(4) *(Timeline for reporting an illegitimate product)* The proposed language requires pharmacies to report an illegitimate product within	The Board expects a licensee to follow federal law and report to the Board when they also report to the FDA. Therefore, the language in the rule has been adjusted to reflect that the Board must

		24 hours from the date it is determined illegitimate in coordination with the manufacturer. While UH supports timely reporting, pharmacy leaders note that contacting a manufacturer, receiving confirmation, and gathering the required information may take longer than 24 hours - especially on weekends, holidays, or when manufacturer response times vary. For operational feasibility, UH recommends revising the timeline as follows: “Report within 72 business hours from the date the pharmacy receives confirmation from the manufacturer that the product is illegitimate.” This maintains timely reporting while ensuring pharmacies have adequate time to complete the necessary verification steps. Thank you again for the opportunity to provide comments. UH appreciates the Board’s continued	be notified within 24 hours of notification to FDA. This ensures that state and local authorities are notified within the same timeframe and following the same process.

		collaboration and commitment to supporting safe and effective pharmacy practice across Ohio. We look forward to ongoing partnership as these rules advance.	
Andrea Sidun, RPh, PharmD	Summa Health Home Infusion	"Rule 4729:5-5-11 | Prescription transfers. (NEW) (RESCIND CURRENT) Section (E) (2) Unless otherwise prohibited by law, no pharmacy shall refuse to transfer information about a prescription to another pharmacy when requested by the patient, patient's caregiver, or pharmacy acting upon the request of the patient or patient's caregiver. Prescription information shall be transferred in accordance with this rule as soon as possible, but no later than three business days, to ensure that the patient's drug therapy is not interrupted." I believe there should be clarifying language regarding whose responsibility it is to ensure the transfer is completed within three business days (i.e. is it the	The rule was updated to clarify that the timeframe for prescription transfer commences upon the request of the patient, patient's caregiver, or pharmacy representing the patient or patient's caregiver. Therefore, it is clear who the responsibility falls to regarding the prescription transfer. The rule was also amended to allow for pharmacies to confirm with patients or caregivers if a transfer request is made by another pharmacy. This gives pharmacies flexibility if they have policies to try and prevent unauthorized/fraudulent prescription transfers.

		pharmacy giving the transfer or the pharmacy receiving the transfer). I have been in situations where the patient came to the pharmacy and requested we transfer a prescription from another pharmacy to us, and the request was made to the other pharmacy in a timely manner, however the other pharmacy then took several days to complete the request. The three business day rule should also only apply to prescriptions the patient needs filled immediately. Sometimes a patient requests their entire profile be transferred and the prescriptions kept on file for next month, or for the next time they need them. If the prescriptions being transferred are being placed on hold in the patient's profile, the pharmacy should not be made to prioritize the task over other duties that are more immediate.	While the Board understands this concern, the prescriptions are the property of the patient. Therefore, patients must be free to choose where their prescriptions are transferred. Additionally, by allowing pharmacies to parse out what they think is important vs. the patient, it does not consider other steps the patient may need to go through to have their medication filled at the new pharmacy.
Kathryn Kane-Nielson,	Inmar Intelligence	We submit the following comments regarding proposed amendments to OAC 4729:6-3-	

MPH, CT (ASCP)		02, including the proposal to extend the post-discovery filing timeframe from 30 days to 45 days and update the CFR incorporation by reference. **1) Support: Align Ohio's deadline with the federal 45-day DEA Form 106 submission window** We support Ohio's proposal to change the required filing timeframe from 30 to 45 days for theft or significant loss reporting. Today, the rule requires the DEA Form 106 information be filed with the Board within thirty days of discovery. Aligning Ohio's timeframe with the updated federal requirement is a practical compliance improvement because DEA regulations now require a complete and accurate DEA Form 106 be filed within 45 calendar days after discovery (while still requiring initial notice to DEA within one business day). Ohio's proposed text appropriately implements this alignment by changing "thirty"	Supportive Comment

		to “forty-five” days (including for non-controlled dangerous drugs, where Ohio is regulating beyond federal scope). **2) Suggested improvement for the Board’s consideration: a distinct registration pathway for reverse distributors** Separately, we encourage the Board to consider whether Ohio’s licensure structure should include a distinct, clearly defined registration/permit pathway for reverse distributors, rather than treating reverse distribution as a subset of wholesale distribution. <u>Why this distinction matters under federal definitions:</u> Under DEA regulations, “reverse distribute” means acquiring controlled substances from another registrant for the purpose of return to the manufacturer or another registrant authorized to accept returns, or for destruction, and a “reverse distributor” is a DEA-registered	Ohio law creates 5 distinct licensing categories for drug distributors (wholesaler, repackager, 3PL, outsourcing facility, and manufacturer). Therefore, all reverse distributors would have to fall under one of those designations. When reviewing the Board’s licensing rules for drug distributors as part of the 5-year review process, the Board will consider the request to create a distinct subclassification type of reverse distributors.

		distributor that performs those functions. By contrast, the federal "wholesale distributor" definition under DSCSA ties wholesale distributor status to being "engaged in wholesale distribution," and "wholesale distribution" is defined as distribution/receipt of prescription drugs to a person other than the consumer/patient (with specified exclusions). In short: reverse distribution is fundamentally returns/destruction-oriented, whereas wholesale distribution is supply-chain distribution/receipt oriented under the FDCA framework. <u>Ohio's own proposed definitions underscore the conceptual difference:</u> The draft rule text states that shipping dangerous drugs to an Ohio-licensed reverse distributor solely for destruction/disposal "does not constitute a sale" and does not require certain out-of-state shippers to hold an Ohio license. This is consistent with the idea that reverse	

		distribution is not the same activity as wholesale commerce. <u>Other states provide models for a separate reverse distributor category:</u> For example, Georgia has a specific rule governing "Reverse Distributors" (defining the activity as receiving drugs for destruction/return credit/disposal) and separately requires reverse distributors to be licensed/actively permitted. North Dakota likewise identifies a "reverse distributor" as a distinct licensed facility type in its pharmacy rules. Mississippi's pharmacy law has also addressed registration/permit requirements that explicitly include "reverse distributor" as a covered category. **<u>Request:</u>** We recommend the Board open a rulemaking docket (or include in a future package) to evaluate a reverse-distributor-specific license/registration	

		classification with requirements tailored to reverse distribution (returns processing, quarantine/segregation, documentation, destruction oversight), rather than relying on wholesale distribution frameworks that are designed around outbound commercial distribution.	
Patrick Helman, PharmD, MS	Grant Medical Center	Can we please consider addition to pharmacy technicians of all levels in pharmacy technician trainees (3-3-01), registered technicians (3-3-03) and certified technicians (3-3-04) to specifically state that they are allowed to partake as a witness in the disposal/waste of controlled substances? In 4729:5-3-01, pharmacy technicians are not specifically mentioned, whereas nursing personnel and correctional facility officers (alongside pharmacists and others) may partake in the disposal process. DEA regulations do not restrict technicians from partaking in the Form 41 process, therefore, I would like the regulations to specifically call out this action in the	OAC 4729:5-5-24 and OAC 4729:5-9-02 permit a pharmacist and any other registered healthcare professional to conduct and witness the disposal of controlled substances. Specifically, the current pharmacy record keeping rules state: (1) If the disposal of controlled substance drug inventory is performed on-site in an institutional pharmacy, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal, one of whom shall be a pharmacist.

		permissible actions of a pharmacy technician.	(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient in an institutional pharmacy, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal. Registered healthcare professionals include technicians from all registration levels. See page 84 of the institutional pharmacy inspection guide. Therefore, this comment was not incorporated into the rule.
Aaron Roberts, PharmD	The Christ Hospital Health Network	I am writing to recommend that the proposed changes be discarded to Rule 4729:1-6-02 Section (A) (1) (e): A description of the types of tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the collaborating managing pharmacist. **Tests may only be ordered and**	

		evaluated if the tests relate specifically to the management of a patient's drug therapy. as long as the tests relate to the management of drug therapy. ~~**This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement.**~~ I am an ambulatory care pharmacist working in oncology at The Christ Hospital Health Network. In this capacity, I practice under a CPA to help manage patients on oral oncolytic therapies ensuring that doses are appropriate, toxicities and side effects are effectively managed, and that the overall treatment plan is safe for the individual patient. These treatment regimens are often complex and require laboratory testing that may not directly relate to the medication that I am managing. One example would be immunosuppressant agents that have a risk of reactivating latent Hepatitis B infections.	

		Screening at baseline is important for patient safety though it would not directly impact the drug therapy itself; it would simply prompt additional management. Another example is thyroid toxicity from broad spectrum tyrosine kinase inhibitors. For many patients, these agents are their last line of therapy. Damage to the thyroid gland can sometimes necessitate supplementation with levothyroxine and is not a reason to change cancer treatment itself. Checking this lab is critical for patient safety even though the results would not change the dose or frequency of the oncolytic medication. The proposed change in this rule unnecessarily hampers clinical pharmacists such as myself by introducing ambiguity to what we are allowed to do and limiting our ability to provide comprehensive care to patients. This introduces risk to the patients we serve and increases the burdens on our providers.	

		The original wording already requires that the tests we order be described and reviewed by participating physicians, which I feel is sufficient to protect patients from pharmacists ordering inappropriate tests. For the above reasons, I recommend AGAINST the proposed rule change to this section in favor of maintaining the original wording.	
Emily Pierson, PharmD, BCPS, BGCP, BCACP	The Christ Hospital Health Network	Regarding the proposed changes to rule 4729:1-6-02, as it pertains to subsection (A)(1)(e), I would like to express that in my professional opinion this change is a set back to the practice of pharmacy. The proposed changes now dictate that the pharmacist in a collaborative practice agreement justify each test ordered and how it may relate to a specific drug. Not only is this not necessary, but it also limits the pharmacist in what they are able to order. In theory, limiting the pharmacist ability to order tests that "relate specifically to the	

		management of a patient's drug therapy" sounds good, in practice it is not. Ordering a urine microalbumin is extremely important for the overall care and health of a patient with type 2 diabetes, however it does not necessarily relate to a specific medication used for the care of diabetes. It does help me in my daily practice show patients how their disease has impacted their renal function and motivate behavior change. This is but one specific example of how this is going to impact the practice of pharmacists in Ohio. We will now have to justify to the board why a test/lab was ordered and how it "relate[s] specifically" to drug management. This doesn't include the medications that require extensive lab monitoring and test ordering prior to initiation (antipsychotics, antiretrovirals, antibiotics, etc). I implore the board to leave the verbiage as is. This leaves the determination of what labs	

		and tests are appropriate for a pharmacist to order largely up to the collaborating practitioner, the pharmacist, and the health system that employes them both. Overregulating collaborative practice agreements unnecessarily limits pharmacists in this unique sector.	
Kelsey Fletcher PharmD, BCCP	The Christ Hospital Health Network	I am an ambulatory care clinical pharmacist who works under the scope of collaborative practice agreements in Ohio. I would like to comment on the portion of this proposed rule change which would clarify that testing ordered must be related specifically to the management of a patient's drug therapy. There are examples in my practice for which labs necessary for comprehensive patient management may be indirectly related to drug therapy. For example, I see patients for heart failure guideline directed therapy medication adjustment. An example of a laboratory order which would be indirectly related to medication	

		management, but still affect management would be BNP/NT-pro-BNP to assess fluid status in the setting of symptoms not being in line with physical assessment. There are several other examples which would affect the ability for myself any my colleagues to care for our patients to the best of our ability. I would like to advocate for this proposed rule change to be reconsidered. Please contact me with any questions.	
Jennifer Wick	The Christ Hospital Health Network	Thank you for the opportunity to provide feedback on the proposed revisions to Rule 4729:1-6-02 governing consult agreements. I appreciate the Board's ongoing work to ensure safe, effective, and appropriately regulated pharmacist-provided care. I would like to express concern regarding the proposed change to paragraph (E), which would revise the rule to read: "Tests may only be ordered and evaluated if the tests	

		relate **specifically** to the management of a patient's drug therapy." While I understand and support the Board's intention to ensure that testing ordered by pharmacists remains within the scope of drug-therapy management, the phrase "specifically relate to" may unintentionally narrow clinical practice in ways that could limit optimal patient care. Pharmacists frequently rely on diagnostic or clinical tests that inform the selection, initiation, or modification of drug therapy, even when those tests do not directly measure the effect of a specific medication. For example: • In a patient with diabetes, ordering a C-peptide test helps determine endogenous insulin production. Although this test is not a direct monitoring parameter for any particular drug, the result has utility in deciding between insulin therapy and agents which rely	

		on augmenting endogenous insulin action. • In a patient using carbamazepine for seizure prevention, determining hepatic function and calculating a Child-Pugh score are essential for safe dosing. Although the diagnosis of liver disease may be known, the patient may not have a formal Child-Pugh classification on file. To complete this assessment, the pharmacist may need to order labs such as albumin, INR, and bilirubin, which are not direct monitoring parameters for carbamazepine but are critical for selecting an appropriate and safe dose. • In a patient with chronic hepatitis B who requires treatment for hepatitis C, ordering HBV-related labs is essential to evaluate reactivation risk prior to initiating HCV therapy. While these tests are not specific monitoring parameters for any hepatitis C agent, the results are vital in determining whether HBV prophylaxis or concurrent therapy is necessary before	

		selecting and starting an appropriate HCV regimen. • Similar scenarios arise in heart failure, neurology, and anticoagulation management, where test results guide therapy decisions even if they are not tied to a specific drug's pharmacokinetic/ pharmacodynamic profile. Under the proposed wording, these clinically appropriate, mechanism-guided decisions might be interpreted as falling outside the pharmacist's permissible authority because the tests do not "specifically" measure or monitor a particular drug. This could inadvertently restrict pharmacists from ordering tests necessary to determine the most effective and safe therapy for a patient. To maintain the Board's intent—ensuring pharmacists order tests only for drug-therapy management—while avoiding unintended limitations, I respectfully propose alternative wording that mirrors the current rule's flexibility:	

		"Tests may be ordered and evaluated by the collaborating pharmacist when the results are reasonably expected to inform or impact the management of a patient's drug therapy." **or** **"Tests may be ordered and evaluated as long as they relate to or support decisions involving the management of drug therapy, including tests that assist in determining appropriate drug selection, dosing, or therapeutic adjustments."** This language preserves appropriate boundaries while ensuring that pharmacists can continue to use necessary clinical data to make evidence-based drug-therapy decisions. Thank you for your consideration and for your continued commitment to protecting the health and safety of patients in Ohio.	

OAC 4729:1-6-02 – Comment Discussion

Statute	Current Rule	Proposed	Commenter Suggestions
Order laboratory and diagnostic tests, including blood and urine tests, that are related to the drug therapy being managed, and evaluate the results of the tests that are ordered.	A description of the types of tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement.	Tests may only be ordered and evaluated if the tests relate specifically to the management of a patient's drug therapy.	"Tests may be ordered and evaluated by the collaborating pharmacist when the results are reasonably expected to inform or impact the management of a patient's drug therapy." OR "Tests may be ordered and evaluated as long as they relate to or support decisions involving the management of drug therapy, including tests that assist in determining appropriate drug selection, dosing, or therapeutic adjustments."

Rule 4729:5-4-02 | Duty to Report. (AMEND)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Dispensing error" or "error in dispensing" has the same meaning as rule 4729:5-3-22 of the Administrative Code.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(4) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(B) A pharmacy licensed as a terminal distributor of dangerous drugs shall be required to report, from direct observation or objective evidence, the following to the board in accordance with paragraph (C) of this rule:

(1) Any error in dispensing when the error is the result of reckless behavior.

(2) Any error in dispensing where the error results in any of the following per the "National Coordinating Council for Medication Error Reporting and Prevention Medication Error Index (Revised 2/20/2001)":

(a) Category G: an error occurred that resulted in permanent patient harm.

(b) Category H: an error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest).

(c) Category I: an error occurred that resulted in patient death.

(3) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on an error or errors in dispensing.

(4) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on engaging in unprofessional conduct, dishonesty, or reckless behavior.

(5) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on conduct indicating an individual licensed or registered by the board is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(6) The receipt of a prescription or medication order where a pharmacist refuses to dispense the prescription or medication order on the basis that it is or is suspected to be fraudulent. Examples of fraudulent prescriptions include, but are not limited to, prescriptions that are forged, altered, or counterfeit.

(7) The receipt of an illegitimate product as defined in 21 U.S.C. 360eee (November 27, 2013) and the United States food and drug administration guidance: "definitions of suspect product and illegitimate product for verification obligations under the drug supply chain security act guidance for industry" (March 2023).

(C) Reporting required in accordance with this rule shall be made by mail, using the board's online complaint form (available on the board's website: www.pharmacy.ohio.gov), or telephone and shall include the following information:

(1) For violations listed in paragraphs (B)(1) through (B)(5) of this rule:

(a) The name of the ~~**employer**~~ **pharmacy** and the **pharmacy's** ~~**employer's**~~ terminal distributor license number;

(b) If applicable, the full name and license or registration number of the licensee or registrant for which a report is being made;

(c) If applicable, an explanation of the error in dispensing that occurred, including details regarding any patient harm;

(d) If applicable, an explanation of the circumstances that resulted in the individual's termination or resignation from employment; and

(e) The date(s) of and place(s) of occurrence(s), if known.

(2) For violations listed in paragraphs (B)(6) of this rule:

(a) The name of the pharmacy and the pharmacy's terminal distributor license number;

(b) A description of the prescription or order that is or is suspected to be fraudulent;

(c) Name and address of the issuing prescriber; and

(d) The date the prescription or order was received.

(3) For violations listed in paragraph (B)(7) of this rule, the pharmacy shall submit a copy of the required form FDA 3911 (May 2023).

(D) All reports submitted in accordance with this rule shall protect the confidentiality of patients. The Board may request additional information, including patient information, as part of an investigation conducted in accordance with Chapter 4729. of the Revised Code.

(E) All required reporting shall be submitted to the board no later than:

(1) For an error in dispensing pursuant to paragraphs (B)(1) to (B)(3) of this rule, ten days from the date the quality assurance program review in accordance with rule 4729:5-3-22 of the Administrative Code was completed; and

(2) For the termination or resignation of an employee pursuant to paragraphs (B)(4) and (B)(5) of this rule, ten days from the date the individual is terminated or resigns from employment.

(3) For the receipt of a fraudulent or suspected fraudulent prescription or medication order, ten days from the date the pharmacist refused to dispense the prescription or medication order.

(4) For the receipt of an illegitimate product, within twenty-four hours from the date the pharmacy submits the required form FDA 3911 (May 2023).

(F) Notwithstanding any provision of agency 4729 of the Administrative Code, a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee shall not be required to make a report to the board pursuant to the applicable duty to report rules in divisions 4729:1, 4729:2, and 4729:3 of the Administrative Code if the licensee or registrant is employed by or under contract with a pharmacy licensed as a terminal distributor of dangerous drugs and the terminal distributor submits a report in accordance with this rule.

(G) In accordance with section 4729.23 of the Revised Code, information submitted to the board in accordance with this rule shall be deemed confidential, is not a public record, and is not subject to discovery in any civil action.

Rule 4729:5-5-11 | Prescription transfers. (NEW) (RESCIND CURRENT)

(A) An outpatient pharmacy may transfer prescriptions in accordance with the following:

(1) Prescriptions may only be transferred between pharmacists, except as follows:

(a) Pharmacy interns may transfer non-controlled prescriptions in accordance with paragraph (H) of this rule; and

(b) Certified pharmacy technicians may transfer non-controlled prescriptions in accordance with rule 4729:3-3-04 of the Administrative Code.

(2) Transfers of controlled substance prescriptions shall be communicated directly between two pharmacists in accordance with all applicable federal regulations.

(B) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(C) Transfers are subject to the following requirements:

(1) The transferring pharmacist, pharmacy intern, or certified technician shall do the following:

(a) Write the word “VOID” on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(b) Record on the reverse of the invalidated prescription the name, address, name of the pharmacist, pharmacy intern, or certified technician receiving the prescription information, and, if applicable, the DEA registration number of the pharmacy to which it was transferred; for electronic prescriptions, such information must be added to the prescription record.

(c) Record the date of the transfer and the name of the pharmacist, pharmacy intern, or certified pharmacy technician transferring the information.

(d) Ensure copies of controlled substance prescriptions may only be transferred if the prescription record in the system is invalidated to prevent further dispensing at the original pharmacy.

(2) For paper prescriptions and prescriptions received orally and reduced to writing, the pharmacist, pharmacy intern, or certified pharmacy technician receiving the transferred prescription information must write the word “transfer” on the face of the transferred prescription and reduce to writing all information required to be on a prescription pursuant to rule 4729:5-5-15 of the Administrative Code and include:

(a) Date of issuance of original prescription;

(b) Original number of refills authorized on original prescription.

(c) Date of original dispensing.

(d) Number of valid refills remaining and date(s) and locations of previous refill(s).

(e) Pharmacy's name, address, DEA registration number if transferring a controlled substance, and the serial prescription number from which the prescription information was transferred.

(f) The full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(g) Pharmacy's name, address, DEA registration number if transferring a controlled substance, and the serial prescription number from which the prescription was originally filled.

(3) For electronic prescriptions being transferred electronically, the transferring pharmacist, pharmacy intern, or certified pharmacy technician shall provide the receiving pharmacist, pharmacy intern, or certified pharmacy technician with the following information in addition to the original electronic prescription data as required by rule 4729:5-5-15 of the Administrative Code:

(a) The date of the original dispensing.

(b) The number of refills remaining and the date(s) and locations of previous refills.

(c) The transferring pharmacy's name, address, DEA registration number if transferring a controlled substance, and prescription number for each dispensing.

(d) The full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(e) The name, address, DEA registration number if transferring a controlled substance, and prescription number from the pharmacy that originally filled the prescription, if different.

(f) The contents of the prescription shall not be altered during transfer between pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(D) A prescription may be transferred by the use of a facsimile machine. A facsimile shall be considered a copy of the prescription if it meets the requirements of paragraph (C)(1) and (C)(2) of this rule, including invalidation of the original prescription. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(E) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient.

(1) If the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacy shall, upon the request of the patient or patient's caregiver, transfer the prescription information to a pharmacy designated by the patient.

(2) Unless otherwise prohibited by law, no pharmacy shall refuse to transfer information about a prescription to another pharmacy when requested by the patient, patient's caregiver, or pharmacy acting upon the request of the patient or patient’s caregiver. Prescription

information shall be transferred in accordance with this rule as soon as possible, but no later than three business days, to ensure that the patient's drug therapy is not interrupted.

(a) The transfer of a prescription shall be considered to be initiated upon the request of the patient, patient's caregiver, or pharmacy acting upon the request of the patient or patient's caregiver in accordance with paragraph (E)(2) of this rule.

(b) A pharmacy that receives a request to transfer from another pharmacy reserves the right to confirm the transfer with the patient or patient's caregiver prior to initiating a transfer. In this instance, the transfer shall be considered to be initiated upon confirmation by the pharmacy with the patient or patient's caregiver.

(3) A prescription may only be transferred upon the request or consent of the patient or patient's caregiver.

(F) The transfer for initial dispensing of an electronic prescription for a controlled substance in Schedule II-V is permissible between pharmacies, upon request from the patient, on a one-time basis only. If the transferred prescription is for a controlled substance in Schedule III, IV, or V and includes authorized refills, the refills are transferred with the initial prescription to the pharmacy receiving the transfer.

(G) The transfer of an electronic prescription between pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one pharmacy to another pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription for a controlled substance to another form (*e.g.,* facsimile) for transmission.

(2) The contents of the prescription shall not be altered during transfer between pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) For controlled substances, the transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist, pharmacy intern, or certified pharmacy technician must add the following to the electronic prescription records maintained by the transferring pharmacy:

(a) Information that the prescription has been transferred.

(b) The name, address, the name of the pharmacist, pharmacy intern, or certified pharmacy technician receiving the prescription information, and, if transferring a controlled substance, the DEA registration number of the pharmacy to which the prescription was transferred.

(5) The receiving pharmacist, pharmacy intern, or certified pharmacy technician shall do the following:

(a) Add the word “transfer” to the electronic prescription record at the receiving pharmacy.

(b) Annotate the prescription record with the name, address, and, if receiving a controlled substance, the DEA registration number of the pharmacy from which the prescription was transferred.

(c) Record the full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(c) Record the date of the transfer and the name of the pharmacist, pharmacy intern, or certified pharmacy technician receiving the prescription information.

(6) In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the information required, as outlined in this paragraph, from the electronic prescription and automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. The transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

(F) Transfer of prescription information between two pharmacies which are accessing the same real time, online database pursuant to the operation of a licensed central fill pharmacy

shall not be considered a prescription transfer and is not subject to the requirements of this rule.

(G) Records documenting the transfer prescriptions shall be maintained for three years from the date of transfer or receipt, in a readily retrievable manner, by both the pharmacy transferring the prescription and the pharmacy receiving the prescription.

(H) A licensed pharmacy intern may transfer and receive transfers for non-controlled prescriptions in accordance with the following:

(1) The pharmacist on duty who is supervising the activity of the intern determines if the intern is competent to engage in such activities.

(2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription transfer that is sent or received by the intern.

(3) The pharmacist on duty must be immediately available to answer questions or discuss the prescription transfer that is sent or received by the intern.

(4) The pharmacist or intern receiving a prescription transfer from an intern must document the full names of the intern and the intern's supervising pharmacist who transferred the prescription.

(5) The intern receiving a prescription transfer shall immediately transcribe the prescription and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the supervising pharmacist on duty shall be recorded to identify who is responsible for the receipt of the transfer.

(6) The pharmacist or intern transferring a prescription to an intern must document the full names of the receiving intern and the pharmacist on duty.

(7) The intern shall not transfer or receive a transfer for a controlled substance prescription.

(8) The intern and the pharmacist on duty shall comply with all the requirements of this rule.

Rule 4729:6-3-02 | Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. (AMEND)

(A) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the administrative code shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss;

(2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (~~**9/9/2014**~~ **June 22, 2023**);

(3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

(B) The theft or significant loss of controlled substances by a licensee shall be reported by using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss.

(1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within ~~**thirty**~~ **forty-five** days.

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(C) The theft or significant loss of non-controlled dangerous drugs shall be reported by a licensee to the state board of pharmacy, in a manner determined by the board, within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

(1) An exemption may be obtained upon sufficient cause if the form cannot be filed within ~~**thirty**~~ **forty-five** days.

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(D) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

(E) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (~~**9/9/2014**~~ **September 30, 2019**) of the theft or loss of DEA form 222.

Rule 4729:1-6-02 | Consult agreements. (AMEND)

(A) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

(a) Identification of the practitioner(s) and pharmacist(s) authorized to enter into the agreement. This may include:

(i) Individual names of practitioners and pharmacists;

(ii) Practitioner or pharmacist practice groups; or

(iii) Identification based on institutional credentialing or privileging.

(b) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

(c) A description of the drugs or drug categories managed as part of the agreement.

(d) A description of the procedures **(i.e., processes)**, decision criteria, and plan the **collaborating ~~managing~~** pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a **collaborating ~~managing~~** pharmacist is allowed to perform under a consult agreement.

(e) A description of the types of tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the **collaborating ~~managing~~** pharmacist**. Tests may only be ordered and evaluated if the tests relate specifically to the management of a patient's drug therapy. ~~as long as the tests relate to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement.~~**

(f) A description of how the **collaborating ~~managing~~** pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification.

(g) A description of how communication between a **collaborating ~~managing~~** pharmacist and practitioner acting under a consult agreement shall take place at regular intervals specified by the practitioner who authorized the agreement. The agreement may include a requirement that a **collaborating ~~managing~~** pharmacist send a consult report to each consulting practitioner.

(h) A provision that allows a practitioner to override a decision made by the **collaborating ~~managing~~** pharmacist when appropriate.

(i) A quality assurance mechanism to ensure that **collaborating ~~managing~~** pharmacists only act within the scope authorized by the consult agreement.

(j) A description of a continuous quality improvement (CQI) program used to evaluate the effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(k) The training and experience criteria for **collaborating ~~managing~~** pharmacists. The criteria may include privileging or credentialing, board certification, continuing education**,** or any other training requirements. The agreement shall include a process to verify that the **collaborating ~~managing~~** pharmacists meet the specified criteria.

(l) An effective date and expiration date.

(2) Institutional **facilities as defined in Chapter 4729:5-9 of the Administrative Code** or **~~ambulatory~~** outpatient facilities **owned and operated by institutional facilities** may implement a consult agreement and meet the requirements of paragraphs (A)(1)(b) to (A)(1)(e) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and made readily retrievable.

(3) The agreement shall be signed by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A **collaborating ~~managing~~** pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(4) All amendments to a consult agreement shall be signed and dated by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A **collaborating ~~managing~~** pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(5) A consult agreement shall be valid for a period not to exceed two years.

(6) Only Ohio licensed practitioners and Ohio licensed pharmacists **physically located in the United States** may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(B) Record keeping. As required by section 4729.39 of the Revised Code, a **collaborating ~~managing~~** pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records and are subject to the confidentiality requirements of rule 4729:5-3-05 of the Administrative Code.

(C) Managing drug therapy.

(1) For the purpose of implementing any actions related to the management of drug therapy listed in division (D)(1) of section 4729.39 of the Revised Code, the **collaborating ~~managing~~**

pharmacist may be authorized as one or both of the following, as specified in the consult agreement:

(a) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile**,** or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement.

(i) For all outpatient prescriptions issued, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.

(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the requirements of ~~**agency 4729**~~ **chapter 4729:5-9** of the Administrative Code.

(b) With respect to non-controlled dangerous drugs only, an agent of the consulting practitioner(s). As an agent of the consulting practitioner(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting practitioner(s), in writing, orally, by a manually signed drug order sent via facsimile**,** or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. A pharmacist issuing a prescription as an agent of a practitioner shall comply with all the following:

(i) For all outpatient prescriptions, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.

(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the prescription requirements of ~~**agency 4729**~~ **chapter 4729:5-9** of the Administrative Code.

(iii) Except as provided in paragraphs (C)(1)(b)(v) and (C)(1)(b)(vi) of this rule, the prescription shall include the required information of the consulting practitioner(s).

(iv) The prescription shall also include the name of the **collaborating** ~~**managing**~~ pharmacist acting as the agent of the consulting practitioner.

(v) The telephone number where the **collaborating ~~managing~~** pharmacist can be personally contacted during normal business hours. The telephone number may be in addition to or in place of the telephone number required by rule 4729:5-5-15 of the Administrative Code.

(vi) Pursuant to the consult agreement, all required positive identification (including a manual signature) on a prescription shall be of the **collaborating ~~managing~~** pharmacist on behalf of the consulting practitioner(s).

(2) If the **collaborating ~~managing~~** pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, a copy of the consult agreement or privileging documentation shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the **collaborating ~~managing~~** pharmacist to act in this manner.

(3) A **collaborating ~~managing~~** pharmacist shall request and review an OARRS report covering at least a one-year time period prior to any of the following:

(a) Adding a controlled substance drug **or a drug containing gabapentin** to a patient's drug therapy; or

(b) Adjusting a**ny of the following for a** controlled substance drug**~~'s~~ or a drug containing gabapentin:** strength, dose, dosage form, frequency of administration, or route of administration.

(4) Except as provided in paragraph (C)(5) of this rule, a **collaborating ~~managing~~** pharmacist shall not delegate drug therapy management to anyone other than another authorized pharmacist practicing under the consult agreement.

(5) A **collaborating ~~managing~~** pharmacist may delegate the administration of a drug to a licensed healthcare professional in accordance with their applicable scope of practice pursuant to the **collaborating ~~managing~~** pharmacist's order.

(6) A **collaborating ~~managing~~** pharmacist authorized to prescribe controlled substances pursuant to paragraph (C)(1)(a) of this rule shall comply with all the following:

(a) Maintain a valid controlled substance prescriber registration issued by the state board of pharmacy by submitting an application and a valid consult agreement, in a manner determined by the board, authorizing the pharmacist to prescribe controlled substances.

(i) A pharmacist shall be required to renew their controlled substance prescriber registration in accordance with a renewal schedule adopted by the board. A controlled substance prescriber registration shall be deemed void if a pharmacist does not renew their registration in accordance with the renewal schedule adopted by the board.

(ii) A pharmacist shall be required to notify the board, in a manner determined by the board, if they are no longer authorized to prescribe controlled substances pursuant to a consult agreement. Notification shall occur within five business days. A controlled substance prescriber registration shall be deemed void if the pharmacist no longer has a valid consult agreement authorizing the prescribing of a controlled substance. Failure to obtain or maintain a valid controlled substance prescriber registration prohibits a pharmacist from prescribing controlled substances.

(iii) A pharmacist applying for a controlled substance registration shall be an Ohio licensed pharmacist in good standing. The pharmacist shall not be the subject of any current board disciplinary action or have a restricted license. In determining whether to grant a registration, the board may consider any previous disciplinary action.

(iv) The board may deny a registration if the applicant fails to meet any of the required qualifications or if the board finds that issuing a controlled substance registration presents a danger to public safety.

(b) Subject to approval by the United States drug enforcement administration (D.E.A.), prescribe utilizing a valid **mid-level** D.E.A. registration**.~~, which includes either:~~**

~~(i) Obtaining and maintaining a valid registration with the D.E.A.; or~~

~~(ii) If authorized by federal law or regulation, a pharmacist who is employed as a staff prescriber of a hospital pursuant to a consult agreement who is not individually registered under the provisions of the controlled substances act and, therefore, does not possess a D.E.A. registration, may administer, dispense, and prescribe controlled~~

~~**substances, as specified in a consult agreement, under the registration of the hospital. A hospital that authorizes a pharmacist to dispense or prescribe under its registration shall assign a specific internal code number for each managing pharmacist so authorized.**~~

(c) ~~**Unless a pharmacist utilizes a hospital's D.E.A. registration,**~~ **F**ailure to obtain or maintain a valid D.E.A. registration shall prohibit a **collaborating** ~~**managing**~~ pharmacist from prescribing controlled substances.

(d) A **collaborating** pharmacist that obtains a valid registration with the D.E.A. pursuant to paragraph (C)(6)(b)~~**(i)**~~ of this rule shall:

(i) Submit the pharmacist's registration information, in a manner determined by the board, within thirty days of issuance.

(ii) Submit any changes to a pharmacist's registration, in a manner determined by the board, within thirty days of any change to the registration.

(7) A prescription, to be valid, must be issued for a legitimate medical purpose by a pharmacist authorized pursuant to a consult agreement. The responsibility for the proper prescribing is upon the **collaborating** ~~**managing**~~ pharmacist, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be considered a violation of this rule and may be subject to disciplinary action in accordance with Chapter 4729. of the Revised Code or any rule promulgated thereunder.

(D) Therapy management by formulary. The requirements of this chapter and section 4729.39 of the Revised Code do not apply within an institutional facility when the pharmacists are following the requirements of a formulary system that was developed pursuant to section 4729.381 of the Revised Code.

(E) Review of consult agreements. Upon the request of the state board of pharmacy, a pharmacist shall immediately provide a consult agreement and any relating policies or

documentation pursuant to this rule and division (D)(3) of section 4729.39 of the Revised Code. The state board of pharmacy may prohibit the execution of a consult agreement if the board finds any of the following:

(1) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or this chapter of the Administrative Code; or

(2) The agreement, if executed, would present a danger to patient safety.