Rules and Resolutions - August 2024

Resolutions

Indicates resolutions was authorized by the Board President in accordance with a Board resolution adopted on May 5, 2020.

1) Temporary Authorization for the Use of Non-Ohio Licensed Pharmacy Personnel by Walgreens*

To mitigate any possible delays due to the closure of Ohio Rite Aid stores, the Ohio Board of Pharmacy hereby authorizes non-Ohio licensed pharmacy personnel employed by Walgreens licensed in other states to work in Ohio Walgreens or Rite Aid stores under certain conditions. This authorization is being issued in accordance with a Board resolution adopted on May 5, 2020.

For the purposes of this authorization, "non-Ohio licensed pharmacy personnel" means an individual who is licensed or registered as a pharmacist, pharmacy intern, or pharmacy technician in another state or jurisdiction, but who does not hold an active Ohio license or registration.

This authorization shall be in effect from the date it is signed by a representative of Walgreens and shall remain in effect until **September 30, 2024**, upon which all Walgreens pharmacists, pharmacy interns, and pharmacy technicians must be appropriately licensed in accordance with Chapter 4729. of the Revised Code.

Pharmacy personnel employed by Walgreens who are not licensed/registered in Ohio, but currently licensed and in good standing in another state, may practice pharmacy in this state under the following conditions:

1. Walgreens shall verify that all non-Ohio licensed personnel are in good standing prior to commencing work in this state. Verification may be done using the online licensing system of the state in which the pharmacy personnel were originally licensed or registered. If licensed/registered in multiple states, verification must be conducted in the state where the individual primarily practices.

NOTE: “In good standing” means the pharmacist does not have a license, registration or certificate limited, on probation, suspended, or revoked by any public agency or licensing agency. "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.

2) Licensure Verification for Institutional Pharmacies Restocking EMS Organizations

To ensure compliance with the licensure verification requirements of OAC 4729:5-3-04 and to reduce operational burden, the Ohio Board of Pharmacy hereby adopts the following resolution for institutional pharmacies and facilities owned or operated by Ohio hospitals:

*An institutional pharmacy **or facility** that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle may satisfy the licensure verification requirements of OAC 4729:5-3-04 by conducting an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs. This resolution shall remain in effect until rescinded by the Board or upon amendment of OAC 4729:5-3-04.*

NOTE: This resolution was adopted by the Board in July. This is a request to update the language to include institutional facilities (freestanding emergency departments) that also stock EMS organizations.

Rules

For filing with the Common Sense Initiative and the Joint Committee on Agency Rule Review.

Rule 4729:5-3-04 | Verification of licensure prior to sale or purchase. (AMEND)

(A) Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the ~~**boards**~~ **board's** online roster (available on the ~~**boards**~~ **board's** website: www.pharmacy.ohio.gov) to confirm any of the following:

(1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code; or

(2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code.

(B) If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code.

If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase.

(C) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729:5-3-09 of the Administrative Code, the terminal distributor shall query the ~~**boards**~~ **board's** online roster (available on the ~~**boards**~~ **board's** website: www.pharmacy.ohio.gov) to determine if the purchaser is licensed as either:

(1) A terminal distributor of dangerous drugs.

For a limited terminal distributor of dangerous drugs license, a terminal distributor shall also review a current version of the **licensee's** ~~**licensees**~~ drug list to ensure the purchaser is authorized to possess the drugs ordered.

(2) A distributor of dangerous drugs in accordance with division 4729:6 of the Administrative Code.

(D) Paragraph (C) of this rule does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:

(1) A terminal distributor, manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor that is located in another state, is not engaged in the sale of dangerous drugs within this state, and is actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business; or
(2) Any of the exempted persons described in section 4729.541 of the Revised Code.

(3) The sale, transfer, or distribution of dangerous drugs to an EMS organization from an institutional pharmacy or facility licensed as a terminal distributor of dangerous drugs that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle if the institutional pharmacy conducts an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs.

(E) A terminal distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons described in section 4729.541 of the Revised Code in accordance with rule 4729:5-3-09 of the Administrative Code and shall ensure the purchaser meets the exemption criteria. To confirm a purchaser meets the exemption criteria, the terminal drug distributor shall comply with ~~**the**~~ **all** the following:

(1) Provide the purchaser, in a manner determined by the board, the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs;

(2) If the purchaser is a prescriber, verify the prescriber is appropriately licensed in this state to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice;

(3) Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section 4729.541 of the Revised Code; and

(4) Ensure that all attestations are maintained by the terminal distributor for a period of three years following the date the attestation is signed by the purchaser.

Rule 4729:5-5-26 | Outpatient Pharmacy Delivery Services (NEW)

(A) As used in this rule,

(1) "Pharmacy delivery agent" means ~~**an employee of the pharmacy,**~~ **the** United States postal service or common **carrier,** ~~**or**~~ contract carrier**, or employee of the pharmacy** who delivers dangerous drugs that have been dispensed **to a patient or agent of the patient**.

(2) "Temperature sensitive drug" means any drug that is required to be stored at temperatures outside of controlled room temperature (59 degrees fahrenheit to 86 degrees fahrenheit).

(B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following:

(1) Contact the patient or patient's caregiver for approval prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services.

(2) Notify the patient or patient's caregiver of the ~~**delivery plan**~~ **date shipped, method of delivery (e.g., mail, courier, drone, etc.),** and expected arrival.

(3) **Take all appropriate measures to** ensure that temperature sensitive drugs, will be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed.

~~**(4) Enclose information informing the patient, if the patient's prescription is a temperature sensitive drug, that it is at risk for damage due to extreme hot or cold temperatures:**~~

~~**(i) During shipment; or**~~

~~**(ii) After delivery to the patient's mailbox or other designated location.**~~

(4) Provide notification to the patient, if the patient's prescription is a temperature sensitive drug, of the timeliness in addressing proper storage of the medication.

(5) Arrange for any controlled substances to require proof of delivery**, which may include the signature of the receiving party.**

(6) Assist patients with arranging access to medication from a local pharmacy if unable to delivery medications in the expected timeframe.

~~**Have a plan in place for local medication supply availability when delivery cannot be accomplished in a timely manner to maintain the patient's ongoing therapy.**~~

(7) Provide a method by which the patient or patient's caregiver can notify the pharmacy as to any irregularity in the delivery of the drug or device, including all of the following:

(a) Timeliness of delivery.

(b) Condition of the drug or device upon delivery.

(c) Failure to receive the proper drug or device.

(8) Ensure there is a process to inform the patient or patient's caregiver within ~~**twenty-four**~~ **forty-eight** hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late.

(C) Any drug or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, the outpatient pharmacy shall take all available steps to mitigate patient harm.

(D) Any drug or device that has been delivered to a patient or is no longer in the possession of a pharmacy delivery agent shall not be returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(E) An outpatient pharmacy shall maintain the following records for all drugs and devices delivered in accordance with this rule:

(1) Patient name;

(2) Patient address;

(3) Prescription number of drug or device being delivered;

(4) Name (brand name or generic) and dosage of each drug or device being delivered;

(5) Name and contact information of the pharmacy delivery agent who performed**, or attempted to perform,** the delivery.

(F) Except for deliveries performed by the United States Postal Service **or common carrier**, an outpatient pharmacy that utilizes a third-party to deliver drugs and devices shall enter into a contract with the third-party to ensure the following:

(1) The required records in paragraph (E) of this rule are ~~**maintained either by the third-party or**~~ **provided to** the contracting pharmacy; and

(2) The third-party entity agrees to cooperate with all investigations regarding the theft or loss of drugs and devices and produce required records listed in paragraph (E) of this rule within three business days of a request by an agent, officer, or inspector of the board.

(G) Theft or significant loss of any dangerous drugs shall be reported to the board in accordance with rule 4729:5-3-02 of the Administrative Code.

Organization	Comment
N/a	Delivery services, especially services like DoorDash/ScriptDrop will return deliveries if patients are not home or refuse delivery. Under Section E, consider adding wording that pharmacies must maintain records of drivers who take possession of RXs and return them to pharmacy (current rule is written so that we must only maintain delivered RX records).
Nationwide Children's Hospital	We appreciate the intent of this rule and provide the following thoughts: B(2) – For shipments, we confirm with the patient the date/time of shipping. We request clarification on what components of the delivery plan the Board would require to be included in the notification. B(3) – We currently test shipments and have documentation for pack outs for 36-hours. Our accrediting body is moving away from requiring test shipments. Additionally, organizations may utilize third party vendors to complete the medication delivery. We propose striking this requirement. We instead propose to include similar language to 4729.9.16 (F). B(4) – How does the Board define "temperature sensitive" drug? All medications contain a temperature storage requirement as defined by the manufacturer and USP. Therefore, would the enclosed disclosure be required for all medications shipped to the patient? B(5) – What methods of "proof of delivery" would be approved by the Board? Currently, we have tracking numbers and can confirm the patient has accepted the delivery. We suggest providing clarity of what constitutes proof of delivery. B(6) – We suggest the following language change "Assist patient with arranging access to medication from local pharmacy if unable to deliver medications in the desired timeframe." Section (C) – As written, the rule implies the pharmacy would bear the replacement costs. Depending on third party use for deliveries (and contractual agreements), there is variability on who would pay the replacement costs or who would provide the replacement med. We suggest modifying the language to state "Any drug or device which is compromised or lost shall be replaced at no additional cost to the patient."
Hims & Hers (via Ohio Pharmacists Association)	Per notice for public comments on the Ohio Board of Pharmacy's proposed rules due January 17, 2024, Hims & Hers offers input after the review of the drafted language in the new **Outpatient Pharmacy Delivery Services** rule (4729:5-5-26). As it relates to the aforementioned proposed rule, we respectfully raise the following:

	Proposed Rule as drafted: (B)(3): Ensure that the drugs will be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed. Comment: There are many external elements which may impact the ability for a drug to be maintained within manufactured temperature ranges, despite exercising best efforts to ensure this occurs. We would suggest revising as follows: "**Exercise best efforts to** ensure that the drugs will be maintained within temperature ranges recommended by the manufacturer until the delivery has been completed" Proposed Rule as drafted: (8) Ensure there is a process to inform the patient or patient's caregiver within twenty-four hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late. Comment: We would suggest allowing entities to have more flexibility around notification, ensuring they provide patients and caregivers with timely - and accurate - information. We would suggest revising to an "as soon as practical upon discovery of the delay" standard. Proposed Rule as drafted:: **(F) (2)** Except for deliveries performed by the United States Postal Service, an outpatient pharmacy that utilizes a third-party to deliver drugs and devices shall enter into a contract with the third party to ensure the following: (2) The third-party entity agrees to cooperate with all investigations regarding the theft or loss of drugs and devices and produce required records listed in paragraph (E) of this rule within three business days of a request by an agent, officer, or inspector of the board. Comment: In (F)(1), the pharmacy has the option of maintaining the records as set forth in paragraph (E). This language suggests the third party is responsible for maintaining and producing these records. We would suggest harmonizing the language to ensure third parties who may not be equipped or have the information to generate these records are not required to produce them. Additionally, it would be beneficial to have a longer timeline for responsiveness to a request, as it may take much longer for the correct individual within an organization to be made aware of said request and to coordinate with the pharmacy to produce the relevant and responsive records. Proposed Rule as drafted:

	(G) Any prescription that is lost, stolen, or otherwise goes missing shall be reported to the board in accordance with rule 4729:5-3-02 of the Administrative Code. Comment: This is a proposed rule which seems to address loss or theft at smaller-scale pharmacies. This would be operationally challenging to capture due to the volume of larger scaled pharmacies, and the broad category of what may be considered a prescription which "otherwise goes missing", which is a hard to define standard. Further, we would suggest limiting reporting requirements of loss or theft to those drugs which have been identified as having potential for abuse, such as those which are controlled substances. We suggest the following edits: "Any prescription **for a controlled substance** that **a pharmacy knows has been** ~~is~~ lost~~,~~ or stolen, ~~or otherwise goes missing~~ shall be reported to the board in accordance with rule 4729: 5-3-02 of the Administrative Code." Thank you for the opportunity to provide feedback throughout this process. If you would like to further discuss, please do not hesitate to contact us with any questions.
Express Scripts	I am writing this letter on behalf of Express Scripts, Inc., and ESI Mail Pharmacy Service Inc. (collectively "Express Scripts", and Accredo Health Group, Inc. ("Accredo") (referred to collectively in this letter as "Express Scripts/Accredo") in response to Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services. **Background:** Express Scripts has been delivering mail-service prescriptions for more than 36 years. During that time, Express Scripts has pioneered and employed innovative technology to ensure the integrity of the medications we ship to patients' homes. For every medication shipped in insulated packaging, Express Scripts uses advanced technology that takes into account the acceptable temperature range for each medication, as well as the forecasted weather patterns the medication will pass through on its journey from an Express Scripts/Accredo pharmacy to the patient's hands. Using a forecasting temperature program with a patented algorithm, shipping and destination temperatures are identified and then matched to the medication's temperature profile. Express Scripts uses this information to determine the appropriate shipping time frame and the packaging that should be used in transit. That technology is used to determine the optimal packaging and delivery methods for temperature sensitive medications, delivered by the Express Scripts and Accredo pharmacies. Express Scripts/Accredo relies on definitions, standards, and guidelines published in the United States Pharmacopeia (USP), as well as stability data and other manufacturer information, to determine if a medication

	will require temperature-controlled packaging based on the range of safe temperatures the medication can endure and the current temperature and weather patterns on the delivery route. **Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services** Express Scripts/Accredo is concerned that sections of the proposed rule are unclear and can lead to unintended consequences, including restricting access to medication and/or delays in care. We appreciate the opportunity to provide the following comments related to Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services: - The definition of *pharmacy delivery agent* in 4729:5-5-26(A) may be read to mean the specific employee of the United States Postal Service, UPS, FedEx or other common carriers. Express Scripts/Accredo believes that such a strict interpretation could adversely impact patients of pharmacies of all sizes, as well as those carrier vendors outside the purview of the Board of Pharmacy in sections 4729:5-5-26 (E) and (F). - Section 4729:5-5-26(F) requires pharmacies enter into third-party contracts with delivery agents which may require new contracts for many pharmacies and/or opening of existing contracts. This could create a barrier to access for patients receiving their medications via delivery either at home or in long-term care or other settings, and from large, medium sized and small pharmacies. Express Scripts/Accredo believes this may lead to an increased financial burden, which would need to be considered throughout the rulemaking. - Section 4729:5-5-26(B)(4) requires the pharmacy to "enclose" information to inform that patient of potential risk to their medications. Express Scripts/Accredo would like to see consistency across states and urges the Board to consider using existing language requiring notice be provided to patients regarding the timeliness in addressing proper storage of their medication. - Section 4729:5-5-26(B)(8) requires the pharmacy to have process to notify the patient within 24 hours of being notified. Our concern is that 24 hours may be too strict a timeframe depending on the practice model or setting. - The proposed rule focuses only on the pharmacy portion of the drug supply chain, without addressing distribution from drug manufacturers to wholesalers and wholesalers to pharmacies. **Recommendation** Express Scripts/Accredo requests that the Board consider the following comments intended to ensure patient safety, including continued access to medications, and help maintain product integrity standardization

	across the supply chain. We also believe these changes provide clarity to pharmacies and pharmacy personnel to best serve our patients. **Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services** **4729:5-5-26(A):** Express Scripts/Accredo believes that such a strict interpretation of 4729:5-5-26(A) could adversely impact patients of pharmacies of all sizes, as well as those carrier vendors outside the purview of the Board of Pharmacy in sections 4729:5-5-26 (E) and (F). We request the Board consider the following language: (A) As used in this rule, "pharmacy delivery agent" means ~~an employee of the pharmacy,~~ the United States postal service~~,~~ or other common carrier, ~~or~~ contract carrier, or an employee of the pharmacy who delivers dangerous drugs ~~that have been dispensed~~ to a patient or an agent of the patient. We believe our recommended language clarifies that a pharmacy may deliver dangerous drugs utilizing the United States Postal Service or other common carrier, a contract carrier or an employee of the pharmacy. Clarifying this definition will also provide a clear reading of 4729:5-5-26(E)(5) reducing the burden of collecting individual information of common carriers, largely unknown to the pharmacy providers. **4729:5-5-26(F):** Express Scripts/Accredo is concerned that 4729:5-5-26(F) requires pharmacies enter into third-party contracts with delivery agents which may require new contracts for many pharmacies and/or opening of existing contracts. We request that the Board considers the following amended language: (F) Except for deliveries performed by the United States Postal Service **or other common carrier**, an outpatient pharmacy that utilizes a third-party to deliver drugs and devices shall ~~enter into a contract with the third-party to~~ ensure the following: (1) The required records in paragraph (E) of this rule are maintained either by the third-party or ~~the contracting~~ pharmacy; and (2) The ~~third-party entity~~ pharmacy agrees to cooperate with all investigations regarding the theft or loss of drugs and devices and produce required records listed in paragraph (E) of this rule within three business days of a request by an agent, officer, or inspector of the board. We believe these recommendations minimize adverse impact to patients and pharmacies, while maintaining the integrity of the Board's intent. We also believe the extended timeline is appropriate for pharmacies that deliver medications and working with vendors and third-parties. Lastly, Express Scripts/Accredo believes requiring pharmacies to enter third-

	party contracts may lead to an increased financial burden, which would need to be considered by the Board. **4729:5-5-26(B)(4)** requires the pharmacy to "enclose" information to inform that patient of potential risk to their medications. To ensure consistency across states, Express Scripts/Accredo urges the Board to consider the following amended language: (B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following: (4) ~~Enclose information informing the patient,~~ Provide notification to the patient, if the patient's prescription is a temperature sensitive drug, of the timeliness in addressing proper storage of the medication. ~~that it is at risk for damage due to extreme hot or cold temperatures or moisture:~~ ~~(i) During shipment; or~~ ~~(ii) After delivery to the patient's mailbox or other designated location.~~ We believe aligning Ohio rule language with that of other states will create consistency for pharmacies and regulators, while meeting the Board's intent to ensure patient's receive information necessary to the handling for their medications. **4729:5-5-26(B)(8)** requires notice within 24 hours. Express Scripts/Accredo feels a hard-line timeframe may be too strict across diverse pharmacy practice models, and therefore asks the Board to consider the following amended language: (B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following: (8) Ensure there is a process to inform the patient or patient's caregiver within ~~twentyfour hours~~ as soon as practicable, but not greater than 72 hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late. While concerns remain with a hard timeline, we feel this alternative language allows flexibility across practice models to ensure the patient gets timely notice of interruptions or delays. As the Board works through the full rulemaking process for Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services, Express Scripts/Accredo encourages the Board to consider all aspects of the pharmacy supply chain, including manufacturers and wholesalers and how they ship or

	deliver the drug product. We believe this will avoid creating an uneven burden on pharmacies while promoting patient safety, ensure continued access to medications and helping to maintain standardization across the supply chain. Thank you for the opportunity to comment on Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services. Please feel free to contact me if you have any questions related to the comments. We look forward to working with the State of Ohio Board of Pharmacy throughout this rulemaking process.
N/a	Section G requires reporting if a delivery is lost or stolen. Is there time to complete an investigation, like 48 or 72 hours. From experience, delivered prescriptions which have been reported as lost are found within a day or 2.
CVS Health	I am writing to you in my capacity as Director of Pharmacy Regulatory Affairs for CVS Health ("CVS") and its family of pharmacies. CVS, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Ohio through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to submit comments on Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services. CVS is supportive and committed to the safe shipping and delivery of prescription medications to patients not only in Ohio, but across the United States, our territories and to our armed services members deployed across the world. CVS has over forty years' experience in safely distributing medications through the mail and has shipped over one billion medications safely to its patients. Over the years, CVS has utilized its vast experience in shipping medications across the country to design unique packing systems for over 400 individual drugs. These packaging systems were created in conjunction and consultation with drug manufacturers and specialty distribution companies. The packaging systems were created utilizing data, science and vigorous testing protocols. The goal of the packaging systems is to duplicate the methods the drug manufacturers use to distribute their product to licensed pharmacies. CVS appreciates the goal of the proposed rule and seeks clarification on several sections as we partner with the Board to ensure safe shipping and delivery of prescription medications without restricting patient's access to prescription medications causing delays in care. Please see the following comments for your consideration: **Rule 4729:5-5-26 Outpatient Pharmacy Delivery Services** **(A).** CVS Health believes the current wording of 4729:5-5-26(A) may lead to multiple interpretations and requests the Board amend 4729:5-5-26(A) as follows:

	(A) As used in this rule, "pharmacy delivery agent" means <u>any of the following who deliver dangerous drugs to a patient or an agent of the patient</u>: 1. An employee of the pharmacy, 2. The United States postal service, or 3. A common or contract carrier. We believe the amended language clearly articulates that a pharmacy may use the United States Postal Service or other common carrier, a contract carrier or an employee of the pharmacy to deliver dangerous drugs. **(B)(4).** CVS Health supports appropriate messaging to patients as to the proper storage and handling of temperature sensitive medications and believe modifying **4729:5-5-26(B)(4)** to mirror existing Georgia Board of Pharmacy language will ensure consistency across states and meet the intent of the Ohio Board. As such we ask the Board to consider amending **4729:5-5-26(B)(4)** as follows: (B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following: (4) <u>Provide notification to the patient, if the patient's prescription is a temperature sensitive drug, of the timeliness in addressing proper storage of the medication.</u> **(E)(5).** CVS Health believes that amending **4729:5-5-26(A)** as indicated above will clarify the requirements of **4729:5-5-26(E)(5),** but without that amendment we feel it may be difficult or overly burdensome for pharmacies to have the specific name and contact information for a pharmacy delivery agent, if the Board defines that term to include: employees of the United States Postal Service or other common carrier. This may also place an undue burden on third-parties outside the purview of the Board. (E) An outpatient pharmacy shall maintain the following records for all drugs and devices delivered in accordance with this rule: (5) Name and contact information of the pharmacy delivery agent who performed the delivery. Again, we believe the amended language offered for **4729:5-5-26(A)** clearly articulates that a pharmacy may use the United States Postal Service or other common carrier, a contract carrier or an employee of the pharmacy to deliver dangerous drugs, and therefore clarifies section **(E)(5)** as well.

	(F)(2) CVS Health has concerns with **4729:5-5-26(F)** in that it requires pharmacies to enter into contracts with third-parties, and then adds specific requirements for those third-parties outside of the purview of the Board. This may increase costs and burden to community pharmacies not currently contracting with third-party vendors, decreasing their delivery options and potentially affecting access to medications for some patients. Due to the timelines of mail and delivery, we also feel a window beyond 3 business days may be warranted. We ask the Board to consider the following language: (F) Except for deliveries performed by the United States Postal Service or other common carrier, an outpatient pharmacy that utilizes a third-party to deliver drugs and devices shall ~~enter into a contract with the third-party to~~ ensure the following: (1) The required records in paragraph (E) of this rule are maintained either by the third-party or the ~~contracting~~ pharmacy; and (2) The ~~third-party entity~~ pharmacy agrees to cooperate with all investigations regarding the theft or loss of drugs and devices and produce required records listed in paragraph (E) of this rule within ~~three~~ 7 business days of a request by an agent, officer, or inspector of the board. Thank you in advance for clarification on the amended rule. We look forward to further opportunities to comment and work with the Board on this rule as the rulemaking process continues. We appreciate the opportunity to provide feedback to the State of Ohio Board of Pharmacy and as always thank you for your support. Please contact me directly at 614-572-9008 if you have any questions.
PCMA (Pharmaceutical Care Management Association)	The Pharmaceutical Care Management Association ("PCMA") appreciates the opportunity to comment on Rule 4729:5-5-26, Outpatient Pharmacy Delivery Services issued by the State of Ohio Board of Pharmacy. PCMA is the national trade association representing PBMs. PCMA's member companies administer drug benefits for more than 275 million Americans, including most Ohioans, who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others. Below are PCMA's comments, concerns, and recommendations regarding specific provisions in Rule 4729:5-5-26. **I. 4729:5-5-26 (A)**

	As Drafted: As used in this rule, "pharmacy delivery agent" means an employee of the pharmacy, United States Postal Service, or common or contract carrier who delivers dangerous drugs that have been dispensed. **PCMA Comments:** We would appreciate additional clarity in this definition. For example, is this meant to be the entity name of the common carrier, or is it meant to be the name of a specific employee of the common carrier? **II. 4729:5-5-26 (B)(1)** **As Drafted:** Contact the patient or patient's caregiver for approval prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services **PCMA Request:** Delete the entire provision. **Rationale for Request:** The requirement to obtain consent prior to billing or delivery is unnecessary and will lead to access to care issues. These pharmacies are sending orders because they have received active engagement from the prescriber or patient. Refill requests submitted by patients and the pharmacy's receipt of a prescription from the prescriber are both steps that take place prior to billing and delivery. With that in mind, the patient will be aware of delivery based on those scenarios. If prescriptions are received from providers and patients, and the pharmacy is unable to reach the patient, this could lead to delays in the patient receiving their medication. This policy was put in place by Medicare Part D some years ago and later modified to not require consent prior to shipping because it increased delivery delays and lapses in therapy. Additionally, the rule implies that this would have to be done in all drug deliveries, even when drugs are suited for ambient conditions Finally, patients have the ability to choose their communication preferences and whether they want to receive notifications. Some patients may choose to not receive these types of notifications from a pharmacy. **III. 4729:5-5-26 (B)(2)** **As Drafted:** Notify the patient or patient's caregiver of the delivery plan and expected arrival. **PCMA Request:** Delete the entire provision **Rationale for Request:** Generally, tracking information is available for these deliveries, and it would make more sense to require a pharmacy to provide a website or phone number where shipping/tracking information can be obtained by a patient. As stated previously, patients have the ability to choose their communication preferences and whether they want to receive notifications. Some patients may choose to not receive these types of notifications from a pharmacy.

	In addition, this requirement makes B-8 (notifying patients of delays within 24 hours) unnecessary. **<u>IV. 4729:5-5-26 (B)(3)</u>** **As Drafted:** Ensure that the drugs will be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed. **PCMA Request:** Reword in the following manner: "(3) Ensure temperature-sensitive drugs will be maintained within recommended temperature ranges until the delivery has been completed." Additionally, we recommend that the entire supply chain should follow the same standards and that this should not be solely focused on the pharmacy aspect. **Rationale for Request:** We feel that the Board needs to include a specific reference to "temperature sensitive drug". See related comments in next section. **<u>V. 4729:5-5-26 (B)(4)</u>** **As Drafted:** Enclose information informing the patient, if the patient's prescription is a temperature-sensitive drug, that it is at risk for damage due to extreme hot or cold temperatures or moisture: (i) During shipment; or (ii) After delivery to the patient's mailbox or other designated location **PCMA Request:** As it is currently written, the proposed rule does not refer to a specific definition of "temperature-sensitive drug." Since the current language is unclear, we recommend deleting the entire provision and replace with the following italicized language: "Pharmacies delivering prescription medications by mail or common carrier *shall ensure that temperature-sensitive prescription medications are delivered to the patient in such a way to ensure the integrity of the medication is not compromised. Temperature-sensitive medications are defined as medications that require storage conditions other than "room temperature storage. Pharmacies delivering prescription medications by mail or common* *carrier shall provide a notification with the delivery providing a toll-free telephone number and/or other means of communication where the patient can contact the pharmacy in regards to the delivered temperature-sensitive medication.* *a) The notification method may be by verbal, written, electronic, or other technological means.* **<u>VI. 4729:5-5-26 (B)(5)</u>** **As Drafted:** Arrange for any controlled substances to require proof of delivery. **PCMA Proposed Suggested Change:** Delete the entire provision

	Rationale for Request: The signature requirement creates delivery delays, and we do not recommend expanding it for that reason. Mandating signature requirements may result in medications not being delivered because someone was not home to sign or may be unable to come to the door at the time of delivery due to a disability or medical concern (e.g., elderly patient not physically able to answer their door or a terminally ill patient on Hospice care). It is also important to think about the potential barriers for individuals living in multiunit housing where getting signatures can be also be challenging. **VII. 4729:5-5-26 (B)(8)** **As Drafted:** Ensure there is a process to inform the patient or patient's caregiver within twenty-four hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late. **PCMA Request:** Based on the proposed edits in 4729:5-5-26 (B)(2) above, PCMA suggests deleting this provision as it is currently written. However, we have provided alternative language in the event the Board wants to maintain this position. If the language is not deleted altogether, delete the entire provision and replace with the following italicized language: *Once it is determined there will be a delay in the delivery of the medication, the patient will be notified.* **Rationale for Request:** Clarifies the intent of ensuring a patient is notified if there is a delay. **VIII. 4729:5-5-26 (C)** **As Drafted:** Any drug or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, the outpatient pharmacy shall take all available steps to mitigate patient harm. **PCMA Request:** Clarify that "compromised" is based on the discretion of the pharmacist. **Rationale for Request:** Clarifies that "compromised" is determined by the pharmacist **IX. 4729:5-5-26 (E)(5)** **As Drafted:** An outpatient pharmacy shall maintain the following records for all drugs and devices delivered in accordance with this rule: (5) Name and contact information of the pharmacy delivery agent who performed the delivery. **PCMA Request:** Delete the entire provision. **Rationale for Request:** We commented on this in 4729:5-5-26 (A) above, but the definition of "pharmacy delivery agent" is unclear. If a common carrier is being used, it is unlikely the carrier would provide the name of the delivery driver because it is unnecessary and also for privacy reasons. We do not believe this level of detail would be feasible for a common carrier to provide.

	X. 4729:5-5-26 (F) **As Drafted:** (F) Except for deliveries performed by the United States Postal Service, an outpatient pharmacy that utilizes a third party to deliver drugs and devices shall enter into a contract with the third to ensure the following: (1) The required records in paragraph (E) of this rule are maintained either by the third party or the contracting pharmacy; and (2) The third-party entity agrees to cooperate with all investigations regarding the theft or loss of drugs and devices and produce the required records listed in paragraph (E) of this rule within three business days of a request by an agent, officer, or inspector of the board. **PCMA Request:** Delete the entire provision **Rationale for Request:** This attempts to put delivery and logistics companies like FedEx under the regulatory authority of the Board of Pharmacy, which the Board does not have the authority to do. Further, it would put the onus on outpatient pharmacies to enforce that authority via contracting which is wholly inappropriate. Additionally, why are the USPS and pharmacy employees (non-third parties) who may be delivering drugs exempted from these same requirements? **XI. 4729:5-5-26 (G)** **As Drafted** (G) Any prescription that is lost, stolen, or otherwise goes missing shall be reported to the board in accordance with rule 4729:5-3-02 of the Administrative Code. **PCMA Request:** Reword in the following manner: "**Theft or significant loss of a prescription should be reported in accordance with rule 4729:5-3-02.**" **PCMA Comment** We believe Ohio already has a requirement of this nature. However, the language as currently drafted implies "all" loss must be reported versus "significant" loss. The suggested change will ensure this language does not conflict with language in the code and will ensure consistency. PCMA appreciates the opportunity to comment on proposed rule 4729:5-5-26. We look forward to a continued dialogue with the Ohio Board of Pharmacy during the rule process. Please feel free to reach out to me with any questions by email at sstephenson@pcmanet.org or by cell phone at 240-909-1544.
The Kroger Co.	The Kroger Co. appreciates the opportunity to submit comments in reference to the Ohio Board of Pharmacy's proposed new rule **4729:5-5-26 Outpatient Pharmacy Delivery Services**. Upon review of this proposed rule, we have identified several issues that we would like to bring to your attention and look forward to working together on workable solutions to the Board's concerns. **(3) Ensure that the drugs will be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed.**

	Outpatient Pharmacy has no access to temperature control processes or results from Manufacturer to Wholesaler or Wholesaler to Pharmacy. We recommend this language be eliminated or changed to focus on controllable factors such as maintaining temperatures from Pharmacy to patient via packaging sufficient to maintain temperature ranges recommended by the manufacturer. **(8) Ensure there is a process to inform the patient or patient's caregiver within twenty-four hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late.** Most major carriers (FedEx, UPS, etc.) do not proactively inform Outpatient Pharmacies if there will be delivery delays. We recommend that this language be eliminated or altered to provide Outpatient Pharmacy more flexibility on the timing for informing the patient "as soon as possible". **(C) Any drug or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, the outpatient pharmacy shall take all available steps to mitigate patient harm.** Package loss is very difficult to define and may be predicated on unreasonable patient expectations versus reality. Without the incorporation of professional judgement, this obligates a pharmacy to undergo financial and regulatory risk regardless of drug schedule, the appearance of fraud or malingering, or carrier delays that are often resolved some time later. It is notable that most major carriers will continue to deliver if they find those packages, resulting in waste or patient risk depending on the drug utilization. There is no concern from for our retail pharmacies – our stores today would replace the product at no cost for the patient but our deliveries are same-day using a single vendor. **D) Any drug or device that has been delivered to a patient or is no longer in the possession of a pharmacy delivery agent shall not be returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.** This has been a long-standing rule in Ohio and seems duplicative. **(F) Except for deliveries performed by the United States Postal Service, an outpatient pharmacy that utilizes a third-party to deliver drugs and devices shall enter into a contract with the third-party to ensure the following:** **(2) The third-party entity agrees to cooperate with all investigations regarding the theft or loss of drugs and devices**

	and produce required records listed in paragraph (E) of this rule within three business days of a request by an agent, officer, or inspector of the board. Such agreements with major delivery companies may be difficult to come to terms on thereby hindering patient access to medications. The major third parties (FedEx, UPS, etc.) will not agree to be bound to the regulations of an entity such as the Ohio Board of Pharmacy that does not regulate them. **(G) Any prescription that is lost, stolen, or otherwise goes missing shall be reported to the board in accordance with rule 4729:5-3-02 of the Administrative Code.** This has been a long-standing rule in Ohio for retail pharmacy and seems duplicative. For outpatient pharmacy, it can be difficult to quickly determine lost vs delayed orders. There is already a DEA notification requirement for lost or stolen controlled substances. We recommend this language be eliminated. In conclusion, The Kroger Co. stands ready to work with the Board to address its concerns on these or other issues in a way that works best for pharmacies, pharmacists, and the patients they serve. Please do not hesitate to contact Jeff Steckman at jeff.steckman@kroger.com if you have any questions.