State of Ohio Board of Pharmacy - Hearing Summary Report

Hearing Date: 6/11/2020

Today's Date: 6/11/2020 – **UPDATED 7/24/2020**

Rule Number(s):

Rule Number	Type	Description
4729:5-20-03	Amend	Security and control of dangerous drugs.
4729:5-3-17	New	Automated pharmacy systems.
4729:5-3-18	New	Dangerous drug recall procedures.
4729:5-4-02	New	Duty to report.
4729:5-5-19	New	Central Fill Pharmacies.
4729:5-5-20	New	Remote Outpatient Prescription Processing.
4729:5-9-02.13	New	Central Fill Pharmacies.
4729:5-9-02.14	New	Remoted Medication Order Processing.
4729-5-28	Rescind	Central fill pharmacies.
4729-5-35	Rescind	Automated drug delivery systems.

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

- CVS Health, 4729:5-5-19
- TelePharm, 4729:5-5-20
- National Association of Chain Drug Stores (NACDS), 4729:5-3-17, 4729:5-5-19, 4729:5-5-20
- Kroger Columbus Central Fill, 4729:5-3-17, 4729:5-5-19

Consolidated Summary of Comments Received

4729:5-3-17

- Kroger Columbus Central Fill – Requested clarification on provisions (B)(2), (F) of the rule. Requested change to tamper-evident be included as an alternative for dangerous drug storage.
- NACDS – Requested the rule to be amended to remove the 45-day auditing periods and 5% daily reviews of automated pharmacy systems.

4729:5-5-19

- CVS Health – Commented that the rule would require that the prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. CVS is recommending to provide one pharmacy of contact while still providing an audit trail for the tracking of the prescription within the pharmacy system the pharmacy could clearly shows the name, address and telephone number of a pharmacy that has access to a patient's record.
- NACDS – Comments that the prescription label requirements be amended to remove the requirement that central fill pharmacies be included.

- Kroger Columbus Central Fill - Recommend adding a disclaimer in the rule that excludes pharmacies from the requirement if they do not fill controlled substances.

4729:5-5-20

- TelePharm – Requested that the definition of Remote Outpatient Prescription processing be expanded.
- NACDS – Requested that the rule be expanding to allow for a pharmacy technician to remote process a prescription. **NOTE:** The Board already issued a waiver permitting this to occur and has already committed to making the necessary rule changes outside of this rule package in order to authorize such a practice.

Other

- NACDS – also included comments for the Board of Pharmacy to adopt emergency rules in response to COVID-19 related vaccination. ***This issue is being addressed in legislation and is not germane to the rule filing.***
- NACDS – amend Ohio Department of Medicaid rules to list pharmacists as eligible providers for telehealth services for both Medicaid and private payer programs and expand telehealth pharmacy services. **The Board cannot address this issue as it is the responsibility of the Ohio Department of Medicaid and therefore the comment is not applicable to this rule filing.**

Incorporated Comments into Rule(s) – UPDATED 7/24/2020

- The rules that received comments (4729:5-3-17, 4729:5-5-19, 4729:5-5-20) have been refiled with JCARR. An overview of these comments, including the Board's decision whether to incorporate the comment into the rule, is included in the chart starting on the next page.

- The rules that did not receive comments will continue along the standard rule adoption process.

Rule Number	Entity	Comment	Response
4729:5-3-17	National Association of Chain Drug Stores	**NACDS Recommendation #1: Remove Arbitrary Requirements on Automated Pharmacy Systems** Rationale: Without evidence that such restrictions promote patient safety, the additional requirements create undue regulatory burden for pharmacies and pharmacists seeking to promote patient care and safety via innovative automated technologies. Arbitrary requirements and excessive administrative burden may limit uptake of new technologies and in turn, hinder innovation more broadly and delay modernized care delivery for patients. Specifically, pharmacy owners/employers are in the best position to determine optimal quality assurance policies and procedures given unique workflow, prescription volume, patient care needs, and the specific automated device being deployed. Further, 45-day auditing periods and 5% daily reviews are arbitrary, and pharmacies should have the flexibility to develop feasible, personalized, ongoing quality assurance procedures without arbitrary requirements and site-specific restrictions. NACDS applauds the Board's directive to support the use of modern pharmacy dispensing technologies including automation; however, benefits to patients and pharmacies can be further enhanced by removing the following undue restrictions: NACDS Suggested Language Modifications (in **red**): **4729:5-3-17 Automated pharmacy systems.** (2) For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(b) of this rule, the responsible person of the	***The Board did not include this comment into the rule.*** As this rule removes the pharmacist from the end verification and relies upon the use of technology, the Board felt it was appropriate to have any automated system undergo evaluation to determine accuracy and ensure patient safety. This rule ensures that any technology is properly reviewed and audited to maximize patient safety. As a reminder, this requirement to test the system prior to implementation **does not** apply to systems that package medications that are verified by a pharmacist prior to sale. Additionally, removing the annual quality control requirements and replacing them with "periodic" does not provide a clear expectation to licensees.

		licensed terminal distributor of dangerous drug shall be required to have a pharmacist verify for accuracy all dangerous drugs dispensed by the system for a continuous ~~forty five day~~ period. The responsible person shall compile metrics, ~~using a form developed by the board,~~ documenting the performance of the system during this period. ~~Unless otherwise approved by the board, the accuracy metrics during the forty five day pharmacy review period shall be no less than ninety-nine and nine hundred eighty-five thousandths (99.985) percent.~~ ~~(3) Approval of all automated pharmacy systems shall be site specific ...~~ (F) For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(b) of this rule, the terminal distributor of dangerous drugs shall implement a quality assurance program to determine continued appropriate use of the automated pharmacy system. The quality assurance program shall monitor the performance of the automated pharmacy system, ensure the system is in good working order and accurately prepares the correct strength, dosage form, and quantity of the drug prescribed or ordered. At a minimum, the quality assurance program shall consist of ~~a review of at least five percent of all dispensed prescriptions over the daily operational hours of the automated pharmacy system.~~ **periodic reviews for acceptable accuracy and proper functionality of the automated pharmacy system....** (3) The utilization of a bar code, electronic verification, or similar	

		verification process shall require an initial quality assurance validation by a pharmacist and shall be followed by **periodic a** ~~**quarterly**~~ quality assurance review**s** by a pharmacist… (7) A registered pharmacy technician or pharmacy technician trainee shall be acting under the ~~**personal**~~ supervision of a pharmacist… (I) Except for an automated pharmacy system in a long-term care facility, a pharmacist shall be physically present at the terminal distributor of dangerous drugs to provide supervision of the automated pharmacy system**, unless the site is authorized for remote dispensing and/or central fill**.	
4729:5-3-17	Kroger Columbus Central Fill	4729:5-3-17 A-2-b *In the case of an automated pharmacy system, the final association will be deemed to have occurred when the pharmacist has given final approval to the patient-specific prescription in the system.* **Recommend this change not be adopted or clarified. Wording could be open to different interpretation and may not align with all technologies facilitating the pharmacist approval process.**	***The Board incorporated this comment into the rule.*** The Board adopted amendments to the rule that incorporated clarification on this issue.
4729:5-3-17	Kroger Columbus Central Fill	4729:5-3-17 B-2 *For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(b) of this rule, the responsible person of the licensed terminal distributor of dangerous drugs shall be required to have a pharmacist verify for accuracy all dangerous drugs dispensed by the system for a continuous forty-five-day period. The responsible person shall compile metrics,*	***The Board did not incorporate this comment into the rule.*** The intent of the Board provided metrics are to ensure accuracy and consistency across all automated systems. Verification means that the drug dispensed by the system matches what was

		using a form developed by the board, documenting the performance of the system during this period. Unless otherwise approved by the board, the accuracy metrics during the forty-five-day pharmacy review period shall be no less than ninety-nine and nine hundred eighty-five thousandths (99.985) percent. **Recommend this change not be adopted or clarified. Unclear what metrics will be required via the Board approved "form". Unclear what qualifies as verification for "all dangerous drugs". If the intent is to allow the automated pharmacy to process orders per system design and then incorporate a separate manual verification process for all fills, this will place undue burden on the facility with significant impact on both staffing and financial resources.** **Any technology issues with pharmacy automation would be detected prior to processing live orders. Ongoing Quality Assurance programs are standard operating procedure. This process will delay the full usage of pharmacy technology and disrupt workflow as originally designed. Disruption in designed workflow can create increased opportunity for error.** **If this language will be adopted, we propose that pharmacy automation system previously approved in the state of Ohio be exempt from this requirement. Also, that the manual verification requirement be reduced to 14 days or less for new systems.**	entered into the system. Additionally, this **DOES NOT** apply to licensees that use pharmacists for final verification and manual verification was already reduced from 90 days to 45 days.

4729:5-3-17	Kroger Columbus Central Fill	4729:5-3-17 F *For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(b) of this rule, the terminal distributor of dangerous drugs shall implement a quality assurance program to determine continued appropriate use of the automated pharmacy system. The quality assurance program shall monitor the performance of the automated pharmacy system, ensure the system is in good working order and accurately prepares the correct strength, dosage form, and quantity of the drug prescribed or ordered. At a minimum, the quality assurance program shall consist of a review of at least five percent of all dispensed prescriptions over the daily operational hours of the automated pharmacy system.* **Recommend this change not be adopted or clarified. Unclear about the definition of "*review of at least five percent of all dispensed prescriptions*." Also, mandating a specific percentage of prescriptions that need to be "reviewed" as part of the quality assurance program could cause a disruption in designed workflow and may create increased opportunity for error.** **Many pharmacy systems have the capability to count thousands of prescriptions per hour. Mandating a manual review of 5% of all dispensed prescriptions in addition to the robust quality assurance measures already included with automated pharmacy systems will significantly impact pharmacist staffing and financial resources.** **Ongoing QA programs are standard operating procedure. We propose**	***The Board did not incorporate this comment into the rule.*** The Board contends that verification is essential to identifying any issues with the system. As a reminder, this requirement to test the system prior to implementation **does not** apply to systems that package medications that are verified by a pharmacist prior to sale.

		the following sentence be removed from this rule. *At a minimum, the quality assurance program shall consist of a review of at least five percent of all dispensed prescriptions over the daily operational hours of the automated pharmacy system.*	
4729:5-3-17	Kroger Columbus Central Fill	4729:5-3-17 H-1 *Except as provided in paragraph (H)(2) of this rule, the container, canister, or other dangerous drug storage device being stocked by the technician, trainee, intern, or nurse is tamper-evident and is verified by a pharmacist and documented using positive identification.* **Recommend this change not be adopted or altered. Some systems use tamper resistant equipment. This is in addition to pharmacist supervision and restricted access to the pharmacy to prevent diversion.** **If this language will be adopted, we propose that "tamper resistant" be included as an alternative.**	***The Board incorporated this comment into the rule.*** The Board adopted a definition of tamper-evident that includes temper-resistant (i.e. if something is tamper-evident it can also be tamper resistant).
4729:5-3-17	Kroger Columbus Central Fill	4729:5-3-17 J *The automated pharmacy system shall have security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and include safeguards to detect the diversion of dangerous drugs. This shall include the use of tamper-evident containers, canisters, or other storage devices for use in long-term care facilities.* **Recommend this change not be adopted or altered. Some systems use tamper resistant equipment. This in addition to pharmacist supervision and restricted access to**	***The Board incorporated this comment into the rule.*** The Board adopted a definition of tamper-evident that includes temper-resistant (i.e. if something is tamper-evident it can also be tamper resistant).

		the pharmacy to prevent diversion. **If this language will be adopted, we propose that "tamper resistant" be included as an alternative. Also, that the last sentence read "This may include…."**	
4729:5-3-17	Cleveland Clinic	We are concerned that this rule could be interpreted to encompass a majority of our mechanical systems. Further, it appears that this rule may require Board approval for any new carousel, robot, or pre-pack system before it is put into use. Thus, we propose that the board strike the terms "storage, packaging, and compounding" from (A)(1) or, further clarify that these terms only apply as related to terminal dispensing of a dangerous drug or prescription. (1)"Automated pharmacy system" means a mechanical system that performs operations or activities, other than administration, relative to ~~storage, packaging, compounding~~, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records.	***The Board did not incorporate this comment into the rule.*** The intent of the rule is to capture automated systems. However, the Board is using the same criteria for the approval of systems as it has in the past. Therefore, systems that have been approved under the old rule should be able to meet the requirements of the new rule.
4729:5-5-19	CVS	Section (B)(6) The prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. The prescription label is a critical part of the medication information for the patient and represents an important component tied to medication adherence. The amount of label space for multiple pharmacy names/locations is	***The Board incorporated this comment into the rule.*** The Board opted to remove this requirement for central fill pharmacies that are owned by the same company. Those that are not commonly owned and controlled have the option to put the name of the central fill pharmacy on the label or as part of documentation

		difficult and may eliminate other important patient required information from the patient's label. The Institute for Safe Medication Practices published recommended industry guidelines for medication labels for community and mail order pharmacies on December 30, 2014[1] in which they suggest maximizing the use of white space on a label to improve medication adherence and reduce inadvertent medication errors. In review of labeling for centrally filled prescriptions, the requirement to "indicate the name and address of the originating pharmacy and the name of the central fill pharmacy" decreases the amount of white space on the label when both pharmacy names/addresses are required. Additionally, different business models may render either of the pharmacies involved in the central fill arrangement to be best suited to serve the patient's need after dispensing. To assist in achieving maximum white space, and better serve the patient by providing one pharmacy of contact while still providing an audit trail for the tracking of the prescription within the pharmacy system the pharmacy could clearly shows the name, address and telephone number of a pharmacy that has access to a patient's record. This would allow for either the originating or central fill pharmacy information based on the pharmacy needs.	accompanying the prescription.
4729:5-5-19	NACDS	**NACDS Recommendation #3: Remove New Label Requirement Likely to Cause Patient Confusion** Rationale: While NACDS appreciates the need for transparency throughout the prescription dispensing process, adding the name of the central fill pharmacy on prescription labels may cause patient	***The Board incorporated this comment into the rule.*** The Board opted to remove this requirement for central fill pharmacies that are owned by the same company. Those that are

		confusion, creates an administrative burden and will detract from already necessary information on labels including patient instruction, warnings, and counseling points. To this end, NACDS suggests removing the requirement that central fill pharmacies must be listed on prescription labels, further, we offer clarifying language on the fill date. Again, we suggest quality assurance programs, policies and procedures are optimally determined by pharmacy employers/owners. Further, we urge the Board to clarify that central fill pharmacies include non-resident pharmacies. NACDS Suggested Language Modifications (in **red**): **4729:5-5-19 Outpatient central fill.** (1) "Central fill pharmacy" means a pharmacy or central filling operation, **including non-resident pharmacies**, licensed as a terminal distributor of dangerous drugs acting as an agent of or under contract with an originating pharmacy to fill or refill a prescription. (6) The prescription label attached to the container shall contain the name and address of the originating pharmacy ~~**and the name of the central fill pharmacy**~~. The date on ~~**which**~~ the prescription **label** ~~**was dispensed**~~ shall be the date on which the central fill pharmacy filled the prescription. ~~**The originating pharmacy shall provide, upon the request of a patient or caregiver, the name and address of the central fill pharmacy and a contact phone number where the**~~	not commonly owned and controlled have the option to put the name of the central fill pharmacy on the label or as part of documentation accompanying the prescription. It should also be noted that the non-resident pharmacy rules (filed on 7/8/2020) were updated to reflect these changes.

		~~patient or caregiver can receive further assistance regarding prescriptions filled by the central fill pharmacy.~~ (10) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems, and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated **on a periodic basis** ~~annually~~**.**	
4729:5-5-19	Kroger Columbus Central Fill	4729:5-5-19 B-2 *The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and drug enforcement administration registration number, for which it processes a request for the filling or refilling of a prescription received by the originating pharmacy. The record shall be made readily retrievable and maintained for a period of three years.* **Recommend adding a disclaimer in the rule that excludes pharmacies from this requirement if they do not fill controlled substances.**	***The Board incorporated this comment into the rule.*** The amended rule makes the requirement to capture DEA number applicable to controlled substances.
4729:5-5-20	TelePharm	4729:5-5-20 - The proposed rule will permit remote outpatient prescription processing in or into the state of Ohio but in a limited capacity for the purposes of remote order entry and data utilization review for an outpatient pharmacy setting. Studies have shown that limited access	***The Board did not incorporate this comment into the rule.*** The intent of the rule is remote processing of prescriptions not telepharmacy.

		to a pharmacy due to transportation, disability, or economic barriers is a hardship for many patients living throughout the United States. 1,2 These barriers lead to decreased medication adherence, and reduced outcomes to therapy. Telepharmacy is an innovative form of pharmacy that can provide or restore access to pharmacy services for medically underserved patients. Telepharmacy includes many other remote processing modalities outside of the provision of order entry and data utilization review. Currently, 25 states permit some form of outpatient remote prescription processing services through telepharmacy. These services include remote supervision of technicians, remote consultations, and remote dispensing, in addition to remote order entry and data utilization review. These forms of telepharmacy enable the pharmacist to provide access to pharmacy services in medically underserved areas with no added change in the scope of practice for a pharmacist or pharmacy technician and without compromising patient safety. Including regulations which allow pharmacists to supervise pharmacy technicians and dispense prescriptions remotely, in addition to the performance of the other tasks specified in the draft rule, will improve access to pharmacy services for residents living in medically underserved areas throughout Ohio, free	

		up the on-site pharmacist to provide more clinical services and provide better care for patients. NABP, APhA, ASHP all include telepharmacy as a form of pharmacy practice either in definition or through guidance as means to increase access to care, and all of these groups contemplate the provision of pharmacy services through remote dispensing in their language. We recommend amending the proposed rule to expand the definition of Remote Outpatient Prescription Processing as follows: *(A) As used in this rule:* *(1) "Remote prescription processing" means the processing of a prescription for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs by a remote pharmacist. Remote prescription processing* ***does not include the dispensing of a drug, but*** *may include receiving, interpreting, evaluating, clarifying* ***, dispensing*** *and approval of prescriptions. Additionally, remote prescription order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions,* ***counseling, supervising technicians,*** *and providing drug information services. The requirements of this rule shall be limited to the processing of outpatient prescriptions*	

		dispensed in or into this state.	
4729:5-5-20	NACDS	**NACDS Recommendation #2: Leverage Skills of Entire Pharmacy Team to Advance Patient Care by Including Pharmacy Technicians and Other Staff in Remote Outpatient Prescription Processing** Rationale: The skills of all pharmacy staff members, including pharmacy technicians, should be leveraged in remote pharmacy operations to perform applicable tasks, as permitted by law. Therefore, NACDS recommends the Board provide examples of remote activities for pharmacy staff, instead of including an exhaustive list of activities. This change would foster innovation and allow remote pharmacy dispensing to appropriately evolve and adapt with technology and the needs of patients, instead of placing undue limitations on specific activities. Further, pharmacy employers are in the best position to determine the specific training needs, policies and procedures, and quality assurance programs given unique characteristics of a pharmacy practice environment. NACDS strongly supports the Board's efforts to advance remote prescription processing. To further enhance meaningful impacts for patients and pharmacies, we suggest the following modifications: NACDS Suggested Language Modifications (in **red**): **4729:5-5-20 Outpatient Prescription Processing.** (1) "Remote prescription processing" means the processing of a prescription	***The Board did not incorporate this comment into the rule.*** The Board, via resolution, already authorizes remote processing for pharmacy technicians and the Board has committed to adopting this resolution into rule later this year. However, to do so, the Board will have to make changes in OAC 4729:3 to avoid conflicting rules. Therefore, such changes will have to wait until fall 2020 when the Board undertakes its review of the pharmacy technician rules.

		for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs by a remote pharmacist **and other applicable pharmacy staff at a remote location, which may include the pharmacist or pharmacy staff's home**. Remote prescription processing does not include the dispensing of a drug, but may include **any task as permitted by law and deemed appropriate for remote means by a pharmacy employer. For example, activities may include** receiving, interpreting, evaluating, clarifying, and approval of prescriptions. Additionally, remote prescription processing may include order entry, other data entry, **third-party adjudication or other third-party requirements,** performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services. The requirements of this rule shall be limited to the processing of outpatient prescriptions dispensed in or into this state… **"Remote Pharmacy Technician" means any of the following:** **(a) If performing remote prescription processing in this state: an Ohio registered pharmacy technician, either employed or a contract employee of an outpatient pharmacy or remote pharmacy, who either assists in processing prescriptions under the supervision of a pharmacist from a remote site, which may include the pharmacist or pharmacy staff's home, or on the premises of a remote pharmacy or outpatient pharmacy; or**	

		(b) If performing remote prescription processing outside of this state: a pharmacy technician registered in the state where the remote prescription processing is occurring, either employed or a contract employee of an outpatient pharmacy or remote pharmacy, who either assists in processing prescriptions under the supervision of a pharmacist from a remote site, which may include the pharmacist or pharmacy staff's home, or on the premises of a remote pharmacy or outpatient pharmacy. (D) An outpatient pharmacy utilizing remote prescription processing shall ensure that all remote pharmacists, **technicians, and other applicable pharmacy staff** providing such services have been trained on the outpatient pharmacy's policies and procedures relating to prescription processing. ~~**The training shall be documented. (1) Such training shall include, but is not limited to, policies on drug and food allergy**~~ ~~**documentation, abbreviations, substitution, and prospective drug utilization review requirements in accordance with rule 4729:5-5-08 of the Administrative Code. The outpatient pharmacy and the remote pharmacy shall jointly develop a procedure to communicate changes in policies and procedures related to prescription processing.**~~ (F) The outpatient pharmacy shall ensure that any remote	

		pharmacist, **technician, or other applicable pharmacy staff** shall have secure electronic access to the outpatient pharmacy's patient information system and to other electronic systems that ~~an~~ on-site ~~pharmacist~~ pharmacy staff has access to when the pharmacy is open. (G) The remote pharmacist must be able to contact the prescriber issuing a prescription to discuss any concerns identified during the pharmacist's review of patient information and the prescription. ~~A procedure must be in place to communicate any problems identified with the prescriber and the outpatient pharmacy…~~ (I) An outpatient pharmacy utilizing remote prescription processing is responsible for maintaining records of all prescriptions entered into their information system, including orders entered by a remote pharmacy ~~pharmacist~~. The system shall have the ability to audit the activities of the remote pharmacy ~~pharmacists~~. ~~(J) … (2) Include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies/pharmacists involved in remote prescription processing; and~~ ~~3.c Maintaining appropriate records of each pharmacists, technicians, and other applicable pharmacy staff pharmacist involved in prescription processing;~~ ~~3c. Annually reviewing the written~~	

		~~**policies and procedures and documentation of the annual review; and**~~ ~~**3f. Annually reviewing the competencies of pharmacists providing remote prescription processing services.**~~	
Other	NACDS	**NACDS Recommendation #4: Remove All Regulatory Barriers to Allow Pharmacies to Optimally Meet the Unique Needs of Patients During the COVID-19 Pandemic** Rationale: The COVID-19 pandemic continues to strain the entire healthcare system on a global scale. For pharmacies, mitigating the exposure of patients and pharmacy staff, and ensuring patient access to medications, testing, and care broadly are the top priorities. To this end, NACDS has compiled a list of targeted recommendations for states to better support pharmacies and patients who rely on pharmacies for access to medirescation and clinical care (***see NACDS white papers, "*****Expanding Access to Patient Care and Ensuring Community Pharmacy Continuity of Operations" and "Pharmacies: A Vital Partner in Reopening America"**). Additionally, in the midst of the COVID-19 pandemic and the public health imperative for social distancing, use of remote pharmacy and central fill dispensing, counseling, and clinical care is ever more important. The ability for pharmacies to provide all facets of appropriate patient care without needless regulatory burden on telepharmacy and telehealth more broadly is necessary. Expanding broad access to pharmacy care is especially	***The Board did not incorporate this comment into the rule.*** The commenter is asking the Board to amend rules of the Ohio Department of Medicaid.

		important for vulnerable patients and to ensure essential continuity of pharmacy operations. This is critically important as healthcare access and capacity continue to be a concern, especially for chronic and preventive care measures, and considering a likely resurgence of COVID-19 this fall. In addressing broad patient needs, NACDS urges states to consider broad sweeping action to support pharmacies to best care for patients throughout this unprecedented time, and a number of states have already removed barriers on telehealth and telepharmacy. Most effectively, this action can be executed in Ohio as outlined below: NACDS Suggested Language for Executive Orders or Board of Pharmacy Emergency Rules: For the purposes of preparing for, responding to, and mitigating any effect of COVID-19, the provisions of Chapter 4729 and any related Ohio statutes and rules promulgated thereunder, that if applied, would operate to limit distribution, dispensing, or administration of otherwise legitimate prescription drugs, vaccines authorized by FDA or medical devices in a manner that could hinder, prevent, or delay mitigation of any health-related condition are suspended for a period of thirty days, and automatically extended unless withdrawn during the pandemic. Specific Recommendations to Foster Enhanced Telehealth Opportunities for Patients Ohio can effectively deploy pharmacists through telehealth by supporting pharmacies within foundational elements	

		of telehealth in applicable rules, as outlined below: **I. Leverage Pharmacists to Enhance Care for Ohio Medicaid Beneficiaries:** In Ohio Medicaid, telehealth is clearly defined in Administrative Code rule 5160-1-18; however, pharmacists are not listed as eligible providers and relevant patient care services are not listed as eligible telehealth services. Further, unlike the private payer requirements in Ohio, the Medicaid program does not offer payment parity language to support the sustainability of telehealth services. There is great opportunity to foster patient access to care in Ohio Medicaid by expanding reimbursable sites that qualify as "originating sites" or "patient sites" to allow patients to access services from community pharmacies, in addition to accessing services from their own homes and other outpatient and community settings. As primary care offices and clinics have been forced to cancel or postpone non-essential visits at times during the COVID-19 pandemic, community pharmacies should be included as both practitioner sites to support pharmacists providing patient care services, in addition to including community pharmacies as patient sites given that pharmacies are essential and remain open during the COVID-19 pandemic. Further, Ohio pharmacists are already partnering with physician groups, health systems, payers, and others to provide access to long-acting injectables, preventive care interventions, and chronic disease state management, for example, amid the COVID-19 pandemic.1 However, implementing the changes below would foster broader access for patients to	

		access care via telehealth. To effectively fill the gaps described above in the Administrative Code, NACDS recommends the following language modifications in **red**: (B) Eligible providers and service locations: (1) The following practitioners are eligible to render services through the use of telehealth: (a) Physician as defined in Chapter 4731. of the Revised Code; (b) Psychologist as defined in Chapter 4732. of the Revised Code; (c) Physician assistant as defined in Chapter 4730. of the Revised Code; (d) Clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner as defined in Chapter 4723. of the Revised Code; (e) Licensed independent social worker, licensed independent chemical dependency counselor, licensed independent marriage and family therapist, or licensed professional clinical counselor as defined in Chapter 4757. of the Revised Code. **(f) Pharmacists, as defined in Chapter 4729, of the Revised Code.** (D) Payment may be made only for the following health care services identified in the appendix to this rule when delivered through the use of telehealth	

		from the practitioner site: (1) When provided by a patient centered medical home as defined in rule 5160-1-71 of the Administrative Code, evaluation and management of a new patient described as "office or other outpatient visit" with medical decision making not to exceed moderate complexity. (2) Evaluation and management of an established patient described as "office or other outpatient visit" with medical decision making not to exceed moderate complexity. (3) Inpatient or office consultation for a new or established patient when providing the same quality and timeliness of care to the patient other than by telehealth is not possible, as documented in the medical record. (4) Mental health or substance use disorder services described as "psychiatric diagnostic evaluation" or "psychotherapy." **(5) Services provided by pharmacists in accordance with applicable state scope of practice laws and attached appendix.** (2) "Patient site" is the physical location of the patient at the time a health care service is provided through the use of telehealth. The patient site shall be one of the following locations: (a) The office or service location of a provider type specified in paragraph (B)(1) of this rule; (b) The patient's home (including but not limited to homeless shelter, assisted	

		living facility, group home, or temporary lodging); (c) School; (d) Inpatient hospital; (e) Outpatient hospital; (f) Nursing facility; ~~or~~ (g) Intermediate care facility for individuals with an intellectual disability (ICF/ IID) or **(h) Community pharmacy.** (3) "Practitioner site" is the physical location of the treating practitioner**,** **including pharmacists,** at the time a health care service is provided through the use of telehealth. The practitioner site shall not be the same location as the patient site. Additionally, NACDS suggest mirroring broad payment parity language from OH Revised Code Annotated, 3902.39 for inclusion and application to Ohio Medicaid. **(1) A health benefit plan shall provide coverage for telehealth services on the same basis and to the same extent that the plan provides coverage for the provision of in-person health care services.** **(2) A health benefit plan shall not exclude coverage for a service solely because it is provided as a telehealth service.** **(C) A health benefit plan shall not impose any annual or lifetime benefit maximum in relation to telehealth services other than such a**	

		benefit maximum imposed on all benefits offered under the plan. **II. Leverage Pharmacists to Enhance Care for Beneficiaries of Private Payer Programs in Ohio.** For private payers in Ohio, telehealth is clearly defined in OH Revised Code Annotated, 3902.30(A)(5), however pharmacists are not included as eligible providers. To rectify this, NACDS suggests the following: (2) "Health care professional" means any of the following: (a) A physician licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery; (b) A physician assistant licensed under Chapter 4731. of the Revised Code; (c) An advanced practice registered nurse as defined in section 4723.01 of the Revised Code. **(d) Pharmacists, as defined in Chapter 4729, of the Revised Code.** **III. Expand Permissible Telehealth Modalities to Full Capacity for Patients.** While live audio and video serve as robust means of virtually providing patient care services, there are circumstances that may limit the use of such. For example, some patients may not have live audio and video capabilities and may prefer other means of communication including email and telephonic care where applicable. Therefore, to support all relevant means	

		of telehealth and communication to meet unique needs and preferences of patients, NACDS suggests the following language modifications: (4) "Telehealth" is the direct delivery of health care services to a patient via secure, synchronous, interactive, real-time electronic communication comprised of both audio and video elements. The following activities are **not also** considered telehealth: (a) The delivery of health care service by electronic mail, telephone call, or facsimile transmission; (b) Conversations between practitioners regarding a patient without the patient present either physically or via secure, synchronous, interactive, real-time electronic communication; **(c) Remote patient monitoring** **(d) Store and forward, to support care coordination.**	