

MISSOURI BOARD OF PHARMACY

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COVID-19 WAIVER UPDATE

(5-20-20)

This has been an unprecedented time for our state and the pharmacy profession. We appreciate all of the Board's licensees and registrants who have risen to the occasion and taken extraordinary steps to take care of Missouri's patients.

Governor Parson has announced implementation of the "Show Me Strong Recovery" plan which outlines steps for gradually and safely reopening Missouri's economy and social activity. As we move past the initial phase of the State of Emergency, the Governor's office has announced the emergency licensing/regulatory waivers issued pursuant to Executive Order 20-04 **will expire on June 15, 2020**.

In line with the Governor's directive, the pharmacy statutory/regulatory waivers listed in [Attachment A](#) will **terminate at midnight on June 15, 2020**. Licensees should begin taking steps to return to normal operational procedures after June 15th.

- The Board recognizes that COVID-19 response efforts are still ongoing. The Board is in the process of requesting approval to extend those waivers that may still be needed during the pandemic, including, waivers issued to accommodate federal COVID-19 allowances/guidance statements (e.g., FDA, CMS). The Board will notify licensees if additional extensions are approved. In the interim, licensees should take immediate action to ensure compliance with Missouri law after June 15th.
- **The Board will honor the July 31, 2020, extended pharmacy technician renewal date.** This means pharmacy technicians will still have until July 31st to renew. Technician registrations not renewed by July 31st will be deemed expired/void and the technician will not be able to work. No grace period will be given after the July 31st deadline due to the extended renewal date.

The following summary lists the waivers that will **be rescinded** and **no longer effective** after June 15th (see [Attachment A](#) for additional details):

- Unlicensed practice by non-resident pharmacists, pharmacy technicians, intern pharmacists and non-resident pharmacies during the State of Emergency
- Substitution of albuterol inhalers with inequivalent FDA-rated inhalers without prescriber approval
- Expanded emergency dispensing allowances, including, dispensing a 60-day emergency supply. **Section 338.200 would apply as enacted.*
- Waiver of designated Class-J Shared Services pharmacy permit and compliance requirements
- Compounding of commercially available products pursuant to the approved waiver
- Compounding without a patient-specific prescription
- Waiver of end-product testing for designated Risk Level 3 preparations
- Dispensing medication without a pharmacist present (even if previously verified by a pharmacist)
- Remote final product verification



- Remote pharmacy technician supervision, and
- Remote data entry by pharmacy technicians/intern pharmacists (e.g., from home). **See additional information below.**

Once again, waiver extensions requests are pending for several of the above items. Licensees will be notified if additional extensions are approved.

Licensees should take precautionary steps to protect patients and pharmacy staff as businesses begin to reopen. The Board strongly recommends using personal protective equipment when possible (gloves, face masks). Licensees should also review the CDC's guidelines for pharmacies available on the [CDC's website](#).

IMPORTANT NOTE ON REMOTE DATA ENTRY: The Board has a pending rule that would allow remote data entry by a pharmacy technician/intern pharmacist. However, the final rule will not be effective until August 2020, due to Missouri's mandatory rulemaking requirements. The Board is discussing legal options to allow remote data entry between June 15, 2020, and the final effective date of the rule in August. Licensees will be notified of any updates. At this time, licensees should prepare to transition all pharmacy technicians/intern pharmacists performing remote data entry activities back to the pharmacy by June 15th.



ATTACHMENT A
MISSOURI BOARD OF PHARMACY
COVID-19 STATUTORY/RULE WAIVERS

(All waivers listed below will expire on **JUNE 15, 2020**. Licensees should take immediate steps to ensure compliance after June 15th. Licensees will be notified if the Board receives approval to grant additional extensions/waivers.)

STATUTE/RULE	WAIVER DESCRIPTION
§ 338.013	<ul style="list-style-type: none"> • Waiver granted to allow Missouri licensed pharmacies to use individuals licensed/registered as pharmacy technicians in another U.S. state or territory to provide pharmacy services during the State of Emergency, provided such non-resident license/registration is current and in good standing. *See Bd. Supplemental guidance (3/23/20) for additional guidelines. • Waiver granted to allow pharmacy technicians licensed/registered in another U.S. state or territory to practice in Missouri during the State of Emergency to assist: <ol style="list-style-type: none"> 1. A hospital or medical care facility that is licensed or owned by the State, and 2. A hospital or medical care facility licensed by the Missouri Department of Health and Senior Services or the Department of Mental Health.
§ 338.020	<ul style="list-style-type: none"> • Waiver granted to allow Missouri licensed pharmacies to use individuals licensed as pharmacists in another U.S. state or territory to provide pharmacy services during the State of Emergency, provided such non-resident license is current and in good standing. *See Bd. Supplemental guidance (3/23/20) for additional guidelines. • Waiver granted to allow pharmacists licensed in another U.S. state or territory to practice in Missouri during the State of Emergency to assist: <ol style="list-style-type: none"> 3. A hospital or medical care facility that is licensed or owned by the State, and 4. A hospital or medical care facility licensed by the Missouri Department of Health and Senior Services or the Department of Mental Health.



STATUTE/RULE	WAIVER DESCRIPTION
§ 338.056/20 CSR 2220-3.011(3)	Waiver granted to allow pharmacists to substitute albuterol inhalers (albuterol sulfate aerosol, metered) with other albuterol inhalers listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) with a different equivalency evaluation code during the State of Emergency if the prescribed albuterol inhaler is not available due to a shortage. This waiver applies only to "albuterol sulfate aerosol, metered" products listed in the Orange book.
§ 338.200.1(2)	<u>Emergency Dispensing:</u> Pharmacies may dispense an emergency supply of medication to a patient if the pharmacy that originally filled the prescription is closed or unable to fill the prescription due to the State of Emergency. Pharmacists must make a good faith effort to verify the medication to be dispensed and the authorized prescriber and dosage form (e.g., as listed on the patient's prescription vial). **This waiver applies to non-controlled substances only; § 338.200 does not apply to controlled substances.**
§ 338.200.2(1)	<u>Emergency Dispensing:</u> Pharmacies/pharmacists may dispense up to a sixty (60) day supply of emergency medication pursuant to § 338.220 during the State of Emergency. For unit of use medications that exceed a 30 day supply, the smallest unit of use available in inventory may be dispensed for emergency purposes. *Supply limit increased from 30 days.
§ 338.220	Waiver granted to allow Missouri licensed pharmacies to use entities licensed as a pharmacy in another U.S. State or territory to assist with providing pharmacy services during the State of Emergency, provided such non-resident license is current and in good standing. Note: A Class-J Shared Services permit is not required during the State of Emergency subject to the requirements identified in the Board's " Waiver of Statutes/Administrative Rules " statement issued on 3/18/20. See also Bd. Supplemental guidance (3/23/20) for additional guidelines.
20 CSR 2220-2.010(1)(A)	Dispensing Verified Medication: Pharmacy technicians or an intern pharmacist may dispense medication to the patient when a pharmacist is not physically present in the pharmacy due to the State of Emergency if: <ol style="list-style-type: none"> 1. The medication has been previously verified by a pharmacist and approved for dispensing, 2. Dispensing is necessary for patient safety or to provide disaster or emergency relief, and 3. Dispensing without the pharmacist present is approved by a pharmacist or pharmacy in advance.



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.010(1)(B)	<p>Remote Product Verification: To prevent illness and staffing shortages, a pharmacist may use technology to remotely verify the final product as required by 20 CSR 2220-2.010 if needed to provide disaster or emergency relief if:</p> <ol style="list-style-type: none"> 1. Physical verification by a pharmacist cannot be promptly performed by a pharmacist; 2. Prompt dispensing is in the best interest of the patient's health and safety; 3. The technology used is sufficient to allow the pharmacist to properly and accurately inspect and verify the accuracy of the contents of the prescription or medication order and the affixed label, and 4. If the pharmacy technician or intern pharmacist is supervised in compliance with proposed rule 20 CSR 2220-2.710 published in the Missouri Register on March 16, 2020. In lieu of the required initial competency assessment referenced in 20 CSR 2220-2.710(2)(C), pharmacy technicians and intern pharmacists must be deemed competent to perform the duties assigned by the pharmacist-in-charge.
20 CSR 2220-2.200(10)(B)	<p><u>Sterile Compounding</u>: Pharmacies engaged in sterile compounding may accept Aseptic Technique Skill Assessment results (including media-fill testing) from another pharmacy for the same staff member, if needed to prevent interruptions in patient care or to ensure availability of pharmacy services during the State of Emergency. However, pharmacy technicians should be trained on pharmacy operational procedures to ensure proper aseptic technique.</p>



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.400(9)	<p data-bbox="472 153 1427 373">Waiver requested to allow Missouri licensed pharmacies to compound commercially available products for hospitalized patients as authorized by and in compliance with the FDA's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency.</p> <ul data-bbox="548 384 1435 863" style="list-style-type: none"> <li data-bbox="548 384 1435 457">• Compounding is limited to the specific drugs listed in the FDA's Temporary Policy <li data-bbox="548 457 1435 646">• Compounding under the FDA's Temporary Policy should only be performed by a Missouri licensed pharmacy if a hospital cannot obtain an FDA approved product or cannot obtain the compounded preparation from a properly registered/licensed drug outsourcer, and <li data-bbox="548 646 1435 863">• The pharmacy notifies the Board in advance of its intent to compound pursuant to the FDA's Temporary Policy. Notifications can be e-mailed to: MissouriBOP@pr.mo.gov and should include the name, address and license number of the compounding pharmacy and the hospital(s) expected to receive the compounded preparations.



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.400(12)	<ul style="list-style-type: none"> • Waiver granted to allow the distribution of compounded preparations by hospital pharmacies without a patient-specific prescription during the State of Emergency in order to: (1) treat COVID-19 patients or patients who have been relocated to other facilities due to the State of Emergency or (2) to assist other hospitals who are unable to provide the compounding services due to the State of Emergency. *For purposes of the waiver, a hospital is defined as a hospital operated by the state or a hospital licensed by the Missouri Department of Health and Senior Services or the Missouri Department of Mental Health or a Class-B pharmacy licensed by the Board. • Waiver granted 4/27/20 to also allow Missouri licensed pharmacies to compound without a patient specific prescription for hospitalized patients in compliance with the FDA's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency, provided: <ol style="list-style-type: none"> 1. The pharmacy complies with FDA's Temporary Policy, including, default beyond-use dating requirements, and 2. Compounding is limited to the specific drugs listed in the FDA's Temporary Policy, and 3. The pharmacy notifies the Board in advance of its intent to compound pursuant to the FDA's Temporary Policy. Notifications can be e-mailed to: MissouriBOP@pr.mo.gov and should include the name, address and license number of the compounding pharmacy and the hospital(s) expected to receive the compounded preparations.



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.200(14)	<p>Waiver granted to allow Missouri licensed pharmacies compounding medication for hospitalized patients pursuant to the FDA's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency, to release Risk Level 3 medication without end product testing results, provided:</p> <ol style="list-style-type: none"> 1. The pharmacy complies with FDA's Temporary Policy, including, default beyond-use dating requirements, and 2. Testing of Risk Level 3 products cannot be completed in sufficient time to provide the requested medication in a timely manner 3. Compounding is limited to the specific drugs listed in the FDA's Temporary Policy, and 4. The pharmacy notifies the Board in advance of its intent to compound pursuant to the FDA's guidance. Notifications can be e-mailed to: MissouriBOP@pr.mo.gov and should include the name, address and license number of the compounding pharmacy and the hospital(s) expected to receive the compounded preparations.



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.650	<p><u>Class-J Shared Services:</u> During the State of Emergency, a Missouri licensed pharmacy may provide shared pharmacy services identified in 20 CSR 2220-2.650 for another Missouri licensed pharmacy without a Class-J Shared Services permit, if the shared services are necessary to prevent interruptions in patient care as a result of pharmacy closures, limited staffing or interruptions in pharmacy operations due to COVID-19. Both pharmacies must comply with 20 CSR 2220-2.650 with the following exceptions:</p> <ol style="list-style-type: none"> 1. A common database or shared real-time access to each pharmacy’s electronic medication or prescription system is not required during the State of Emergency, if such database or real-time access cannot be promptly arranged in sufficient time to meet patient care needs during the State of Emergency. Pharmacists should use their professional judgment to ensure appropriate patient care and medication dispensing. 2. Pharmacies may participate in a shared services arrangement authorized by this directive without a written contract outlining authorized shared services required by 20 CSR 2220-2.650(1)(A)1. or the policy and procedure manual required by 20 CSR 2220-2.650(1)(C)1., if such contract or policy/procedure manual cannot be timely completed to meet patient needs during the emergency. However, authorized shared services should be documented in advance in writing, including, designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. 3. Pharmacies operating under the above allowances must comply with all provisions 20 CSR 2220-2.650 once the State of Emergency ends or upon Board termination of this authorization. A Class-J Shared Services permit and full compliance with the rule will be required at the end of the State of Emergency/Board authorization. <p>*** The above allowances only apply to pharmacies providing shared services to a Missouri licensed pharmacy to prevent interruptions in patient care as a result of pharmacy closures, limited staffing or interruptions in pharmacy operations due to COVID-19. All other pharmacies/shared services arrangements must comply with 20 CSR 2220-2.650.</p>



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-6.055(6)	<u>Non-Dispensing Activities:</u> Pharmacists may use pharmacy technicians and intern pharmacists to assist a pharmacist with non-dispensing functions from an off-site non-pharmacy location during the State of Emergency. Pharmacists should use their professional judgment to ensure technicians/intern pharmacists are appropriately supervised.
20 CSR 2220-2.700(1) & 20 CSR 2220-6.055(6)	<u>Remote Data Entry:</u> Pharmacy technicians and intern pharmacists may perform remote data entry activities from home or outside of a licensed pharmacy, if the pharmacy complies with the provisions of proposed rule 20 CSR 2220-2.725 published in the Missouri Register on March 16, 2020. In lieu of the required initial competency assessment referenced in proposed 20 CSR 2220-2.725(3)(C), pharmacy technicians and intern pharmacists may perform authorized remote data entry functions if approved and deemed competent to perform the duties assigned by the pharmacist-in-charge. See also Bd. Supplemental guidance (3/23/20) for additional guidelines.

