

MISSOURI BOARD OF PHARMACY

MISSOURI BOARD OF PHARMACY COVID-19 WAIVER UPDATE (6-05-20)

The Board previously advised licensees that the pharmacy statutory/rule waivers issued pursuant to Executive Order 20-04 were scheduled to expire on June 15, 2020. To ensure patient care and the availability of pharmacy services, the Governor has approved extending the statutory/rule waivers listed in [Attachment A](#) until [September 1, 2020](#). All other waivers not specifically listed in [Attachment A](#) will expire on [June 15, 2020](#) (see [Attachment B](#)).

The waivers extended until [September 1, 2020](#), include (see [Attachment A](#) for additional details):

- Remote data entry for pharmacy technicians and intern pharmacists (e.g., from home).
- Compounding of commercially available products for hospitalized patients pursuant to the FDA's guidance
- Compounding by pharmacies for hospitalized patients without a patient-specific prescription in compliance with the FDA's guidance.
- Distribution of compounded preparations by hospital pharmacies without a patient-specific prescription during the State of Emergency to treat COVID-19 patients, or to assist hospitals who are unable to provide the compounding services due to the State of Emergency
- Waiver of end-product testing for designated Risk Level 3 preparations for hospitalized patients pursuant to FDA guidance (see Attachment A for additional requirements), and
- Remote final product verification.

NOTE ON REMOTE DATA ENTRY: The Board has a pending pharmacy technician/intern pharmacist remote data entry rule that is scheduled to become effective on August 30, 2020. The extension of the remote data entry waiver listed in Attachment A will allow pharmacy technicians/intern pharmacists to continue performing remote data entry activities off-site, until the Board's permanent rule is effective on August 30th. To prevent interruptions in pharmacy services, the Board has also filed an emergency remote data entry rule that mirrors the waiver. Licensees should monitor the Board's website for additional updates.

Additional Updates:

- **COMPOUNDING FOR HAND SANITIZER:** To help alleviate the shortage due to COVID-19, the Board of Pharmacy will continue to exercise its enforcement discretion and will allow pharmacies and drug outsourcers to compound alcohol-based hand sanitizers for OTC use if the pharmacy complies with the FDA's [Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency](#) and Board rule [20 CSR 2220-2.400 Compounding Standards of Practice](#). A compounding log should be maintained as required by 20 CSR 2220-2.400. The pharma-



cy may note “OTC Use” where the prescription number would normally be recorded on the log. Unless notified otherwise, this exception will continue for the duration of the public health emergency declared by the Secretary of Health and Human Services on January 31, 2020. Once the emergency ends, pharmacies will be required to have a patient specific prescription and comply with all applicable FDA requirements.

- The Board will continue to honor the July 31, 2020, extended pharmacy technician renewal date. This means pharmacy technicians 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.



**ATTACHMENT A
MISSOURI BOARD OF PHARMACY
COVID-19 WAIVER EXTENSIONS**

(All waivers listed below will expire on **September 1, 2020.**)

STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.010(1)(B)	<p><u>Remote Product Verification:</u> 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. <p>EXPIRES (9/1/2020)</p>
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> <p>EXPIRES (9/1/2020)</p>



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.400(9)	<p data-bbox="472 153 1421 373">Waiver granted 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 1421 871" style="list-style-type: none"> <li data-bbox="548 384 1421 451">• Compounding must be limited to the specific drugs listed in the FDA's Temporary Policy <li data-bbox="548 457 1421 640">• 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 1421 871">• 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. <p data-bbox="472 913 771 945">EXPIRES (9/1/2020)</p>



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 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: Missouri-BOP@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. <p>EXPIRES (9/1/2020)</p>



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. <p>EXPIRES (9/1/2020)</p>
20 CSR 2220-6.055(6)	<p><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. Pharmacists should use their professional judgment to ensure technicians/ intern pharmacists are appropriately supervised.</p> <p>EXPIRES (9/1/2020)</p>
20 CSR 2220-2.700(1) & 20 CSR 2220-6.055(6)	<p><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.</p> <p>EXPIRES (9/1/2020)</p>



ATTACHMENT B
MISSOURI BOARD OF PHARMACY
COVID-19 WAIVERS EXPIRING ON JUNE 15, 2020

(All waivers listed below will expire on **June 15, 2020**.
 Licensees should take immediate steps to ensure compliance after June 15th)

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. <p style="text-align: center;">EXPIRES (6/15/2020)</p>
§ 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"> 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. <p style="text-align: center;">EXPIRES (6/15/2020)</p>



STATUTE/RULE	WAIVER DESCRIPTION
§ 338.056/20 CSR 2220-3.011(3)	<p>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.</p> <p>EXPIRES (6/15/2020)</p>
§ 338.200.1(2)	<p><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 <u>not</u> apply to controlled substances.**</p> <p>EXPIRES (6/15/2020)</p>
§ 338.200.2(1)	<p><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.</p> <p>EXPIRES (6/15/2020)</p>
§ 338.220	<p>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.</p> <p>EXPIRES (6/15/2020)</p>



STATUTE/RULE	WAIVER DESCRIPTION
20 CSR 2220-2.010(1)(A)	<p data-bbox="475 195 1421 342"><u>Dispensing Verified Medication:</u> 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:</p> <ol data-bbox="548 348 1421 573" style="list-style-type: none"> <li data-bbox="548 348 1421 422">1. The medication has been previously verified by a pharmacist and approved for dispensing, <li data-bbox="548 428 1421 501">2. Dispensing is necessary for patient safety or to provide disaster or emergency relief, and <li data-bbox="548 508 1421 573">3. Dispensing without the pharmacist present is approved by a pharmacist or pharmacy in advance. <p data-bbox="475 615 787 646">EXPIRES (6/15/2020)</p>



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> <p>EXPIRES (6/15/2020)</p>

