

DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

3 CCR 719-1

STATE BOARD OF PHARMACY RULES AND REGULATIONS

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

30.00.00 TEMPORARY SUSPENSION OF STATE BOARD OF PHARMACY RULES RELATED TO COVID-19

- A. Basis. The basis for this emergency rule is to implement the requirements of Executive Order D 2020-038, issued by Governor Jared Polis pursuant to the State of Emergency Declaration found in Executive Orders D 2020 003, D 2020 027, and D 2020 032, Article IV, Section 2 of the Colorado Constitution, and the Colorado Disaster Emergency Act, sections 24-33.5-701, et. seq., C.R.S., and sections 12-20-204 and 12-280-107(1), C.R.S.
- B. Purpose. This Emergency Rule is adopted to effectuate Executive Order D 2020 038, directing the immediate expansion of the workforce of trained medical personnel available to provide healthcare services due to the coronavirus disease 2019 (COVID-19) pandemic in Colorado.
- C. Pursuant to this emergency rule, promulgated in compliance with Executive Order D 2020 038, the following State Board Pharmacy's Rules are temporarily suspended effective May 1, 2020, for a period of no longer than 120 days:
1. Rule 5.00.60 (which sets forth requirements around closure and notification, which deem a pharmacy to be closed if the compounding/dispensing area is not open for business the minimum number of hours specified in Rule 5.01.40(a));
 2. Rule 5.01.40(a) (which currently requires a minimum number of hours of operation for prescription drug outlets);
 3. Rule 6.00.30 (which sets forth the qualifications for pharmacists to engage in drug therapy management and thereby restricts pharmacists from conducting screening tests for the Coronavirus, so as to ensure that pharmacists may conduct screening tests in pharmacies and other testing centers);
 4. Rule 14.00.80(e) (which currently requires consultant pharmacists to perform consultant pharmacist visits to inspect, and document the inspection, on a quarterly basis for the pharmacy they are managing);
 5. Rule 17.00.30 (which sets forth pharmacist qualifications for collaborative pharmacy practice, including the requirements for education);
 6. Rule 19.01.20 (regarding qualifications to administer vaccines);
 7. Rules 21.20.90(d), (e) and (f) (which sets forth requirements regarding sterile compounding and shortages around garbing supplies so as to ensure compounding pharmacies have adequate supplies).

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8. Rule 26.00.20(g) (which outlines remote pharmacy practice requirements, thereby allowing remote practice without application)
9. Rule 27.00.10(a) (requiring a maximum 1-mile distance restriction between the primary hospital pharmacy and the hospital satellite pharmacy);
10. Rules 27.00.20(c), (e), (f), (i), (j), (k), (l), (m), and (q) (requiring hospital satellite pre-registration inspection as well as various space, technical and reference requirements);
11. Rule 27.00.40 (requiring minimum hours of operation requirement for hospital satellite pharmacies);
12. Rule 27.00.50 (which sets forth hospital satellite pharmacy security requirements); and
13. Rule 29.00.00 (requiring pharmacy technicians to obtain a certification or provisional certification with the Board).

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D. In compliance with Executive Order D 2020 038, the following State Board Pharmacy Rules are temporarily adopted effective May 1, 2020, for a period of no longer than 120 days (any amendments to Board Rules 21.00.00 and 26.00.00 detailed below will supersede applicable language that still exists in the current version of those respective rules during the 120-day time frame);

1. 1.00.25 Colorado-licensed pharmacists may order and administer COVID-19 tests, including serology tests, that have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA), or equivalent regulatory authorization, subject to the disclaimers and limitations required by the FDA for such tests.

2. 21.20.23 Single-Dose and Multiple-Dose Containers.

- a. Opened or needle-punctured single-dose containers shall be used within one hour if opened in worse than ISO Class 5 air quality. ~~Needle-punctured~~ Single-dose containers exposed to ISO Class 5 air quality or cleaner air may be used up to ~~twelvesix~~ hours after initial puncture.

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3. 21.20.70 Environmental Monitoring.

- a. Class 100 or better clean rooms and/or primary engineering controls shall be certified by qualified operators at least every ~~twelvesix~~ months and whenever the device or room is relocated or major service to the facility is performed. Certification records shall be maintained and be available for inspection at the outlet for at least two years from the certification date.
- b. Certification that each ISO classified area is within established guidelines shall be performed no less than every ~~twelvesix~~ months and whenever the primary engineering control is relocated or the physical structure of the buffer area or anteroom has been altered. The testing shall be performed by qualified operators using state-of-the-art electronic equipment with the following results:

- (1) Not more than 3,520 particles 0.5 micrometer size and larger per cubic meter of air for any primary engineering control (ISO Class 5).
- (2) Not more than 352,000 particles of 0.5 micrometer size and larger per cubic meter of air (ISO Class 7) for any buffer room; and
- (3) Not more than 3,520,000 particles of 0.5 micrometer size and larger per cubic meter of air (ISO Class 8) for any anteroom/area.

4. 21.21.40 Storage and Beyond-Use Dating.

- a. The temperature of drug storage areas of CSPs shall be monitored and recorded daily, either manually or electronically. Temperature records shall be maintained and be available for inspection for at least two years.
- b. Finished CSPs that are not immediately dispensed or administered shall be refrigerated or frozen unless their chemical and physical stability are known to be adversely affected by cold or freezing temperatures.
- c. In the absence of sterility testing for each compounded batch compliant with the most current USP/NF Chapter 71 <Sterility Tests>, the beyond-use date (before administration) shall not exceed the following:
 - (1) Low risk CSPs with greater than 12-hour BUD:
Room temperature: No more than ~~4 days~~48 hours
Refrigerated temperature: No more than 14 days
Frozen: No more than 45 days
 - (2) Low risk CSPs with 12-hour or less BUD:
Room temperature: No more than 12 hours
Refrigerated temperature: No more than ~~24~~42 hours
Frozen: Not applicable
 - (3) Medium risk CSPs:
Room temperature: No more than ~~4 days~~30 hours
Refrigerated temperature: No more than ~~10~~9 days
Frozen: No more than 45 days
 - (4) High risk CSPs:
Room temperature: No more than 24 hours
Refrigerated temperature: No more than 3 days

Frozen: No more than 45 days

5. 26.00.10 Definitions

(e) "Remote Pharmacy Practice" may include, but is not limited to, duties conducted by pharmacy interns or pharmacy technicians at a location other than a registered prescription drug outlet or other outlet registered with the Board.

1. Receiving and initially inputting new written, facsimile, or electronic orders;

2. Maintaining proper records for drugs and devices;

3. Transferring prescriptions;

4. Administrative duties that may include, but are not limited to: answering questions telephonically concerning pharmacy hours and operation, processing insurance claims, routing medication questions to the appropriate pharmacist on duty; and

5. Other activities as authorized and defined by the Board by rule.

6. 26.00.20. Requirements for Remote Pharmacy Practice.

- a. A registered prescription drug outlet or other outlet may employ or contract with one or more pharmacists, pharmacy interns, or pharmacy technicians for the purpose of conducting Remote Pharmacy Practice provided that all requirements, including those of confidentiality, privacy, and security are met, as required in this Rule.
- b. All pharmacists, pharmacy interns, or pharmacy technicians employed or contracted with to conduct Remote Pharmacy Practice must ~~be Colorado licensed pharmacists, holding active~~ hold active, unrestricted licenses or certifications with the Board;
- c. No drug inventory shall be stocked or maintained at any Remote Pharmacy Practice location;
- d. Pharmacists, pharmacy interns, or pharmacy technicians engaged in Remote Pharmacy Practice are not considered in the computation of the technician to pharmacist ratio;
- e. All records of Remote Pharmacy Practice must be maintained at the prescription drug outlet or other outlet in accordance with applicable recordkeeping rules;
- f. Remote Pharmacy Practice shall have adequate security and be conducted in a setting sufficient to maintain patient privacy and confidentiality;
- g. Prior to engaging in Remote Pharmacy Practice, the prescription drug outlet or other outlet shall submit a Policy and Procedure Manual and sample Written Agreement to the Board for review. Such Policy and Procedure Manual and Written Agreement must be approved by the

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Board or its designee prior to the prescription drug outlet or other outlet engaging in Remote Pharmacy Practice. Any revisions to the Policy and Procedure Manual and Written Agreement must be approved by the Board or its designee prior to implementation;

- h. Each prescription drug outlet or other outlet which employs or contracts with pharmacists, pharmacy interns, or pharmacy technicians engaged in Remote Pharmacy Practice must maintain a written Policy and Procedure Manual. Such Policy and Procedure Manual shall be reviewed, updated, and revised as necessary to remain current, but at least annually. Written documentation of such review shall be maintained at the prescription drug outlet or other outlet. This policy and procedure manual shall be available for inspection upon request of the Board or its inspectors. This Policy and Procedure Manual shall include the following:
 - 1. Operation of the Remote Pharmacy Practice;
 - 2. Maintenance of security for Remote Pharmacy Practice;
 - 3. Procedure to ensure that Remote Pharmacy Practice shall be conducted in a manner in which patient privacy and confidentiality is maintained, including a provision that patient information may not be printed; and
 - 4. A detailed list of all pharmacists, pharmacy interns, or pharmacy technicians engaged in Remote Pharmacy Practice and contact information for each pharmacist.
- i. The prescription drug outlet or other outlet shall enter into Written Agreements with each pharmacist engaged in Remote Pharmacy Practice, detailing all conditions, and policies and procedures governing Remote Pharmacy Practice. Such agreement shall be reviewed, updated and revised no less than annually. Such agreement shall be maintained at the prescription drug outlet or other outlet and be available for inspection upon request of the Board or its inspectors; and
- j. A pharmacist, pharmacy intern, or pharmacy technician conducting Remote Pharmacy Practice is responsible for ensuring that his or her Remote Pharmacy Practice is conducted in accordance with the Policy and Procedure Manual and Written Agreement.

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Editor's Notes

History

Rules 2.01.10; 2.01.30; 3.00.50; 3.00.70, 6.00.20; 6.00.30; 6.00.40; 8.00.10; 11.04.20; 14.03.10 eff. 07/30/2007.

Rules 8.00.10; 11.04.10; 20.00.00 eff. 09/30/2007.

Rule 4.00.00 eff. 11/30/2007.

Rules 3.01.20, 10.00.00 eff. 03/01/2008.

Rules 5.01.31; 15.01.11; 15.01.12; 15.09.11; 15.09.14; 22.00.00 eff. 05/30/2008.

Rules 4.02.00 (c), 21.00.00, 23.00.00 eff. 06/30/2008.

Rules 1.00.00, 2.00.00, 3.00.00, 5.00.00, 7.00.00, 11.00.00, 12.00.00, 14.00.00 eff. 11/30/2008.

Rule 15.09.11 eff. 01/31/2009.

Rules 6.00.30, 11.06.00, 22.00.00 eff. 03/02/2009.

Rule 9.00.00 eff. 04/30/2009.

Rules 5.00.55, 5.01.31(a), 6.00.20(f), 14.00.40, 15.01.17, 15.01.18, 15.08.19(f), 15.09.11(d), 15.09.15, 15.09.19, 15.09.20(g-h), 15.09.23, 15.09.24, 15.10.10, 16.00.20(d), 19.01.10(b), 19.01.30(a) eff. 12/30/2009.

Rules 4.00, 18.00 eff. 03/17/2010.

Rules 3.00.80 – 3.00.90; 5.00.55; 15.01.12; 19.00.00 – 19.01.50. Rule 22.00.00 repealed eff. 07/15/2010.

Rules 1.00.21, 5.01.31(e), 5.01.50 eff. 08/30/2010.

Rules 5.00.55, 21.11.10 (a), 21.21.70 (a) eff. 11/14/2010.

Rules 1.00.18, 2.01.50 – 2.01.53, 3.00.50 – 3.00.51, 5.00.50, 5.00.60, 5.01.31.a, 11.04.10, 15.01.11, 15.09.11.e eff. 06/14/2011.

Rules 3.01.24, 4.00.00, 11.04.20, 11.04.30, 21.00.00 - 21.11.20, 23.00.00 eff. 04/14/2012.

Rule 14.00.10 eff. 05/15/2012.

Entire rule eff. 01/01/2013. Rule 17.00.00 repealed eff. 01/01/2013.

Rules 3.00.21 – 3.00.22, 3.00.55, 3.00.90.e.(4), 3.01.20.c, 3.01.30, 3.01.32, 3.01.34, 4.00.10.f, 4.00.20, 5.01.31.a.(1)(C), 15.10.14.a, 23.00.90 eff. 09/14/2013.

Rules 2.01.10, 3.00.25, 3.00.91, 5.00.15, 6.00.30, 10.00.00, 11.03.00, 11.07.10, 14.00.05.k-l, 14.00.80.e.(2), 14.00.80.j, 16.00.00, 18.00.00, 20.00.00, 21.00.20, 21.10.80, 21.11.00.a.(12), 21.11.10.c, 21.20.20, 21.20.30.b(14), 21.21.40.c, 21.21.70.c, 21.22.00.b(1), 23.00.30, 23.00.50, 23.00.65, 23.00.70, eff. 10/15/2014.

Rules 3.00.22, 3.00.81.l-o, 3.00.82-3.00.84, 3.00.85.a(3), 3.00.86, 3.00.88.a(2), 3.00.88.b(10), 4.06.00, 6.00.10-6.00.20, 6.00.40.a, 6.00.50, 6.00.60.a, 6.00.60.b.10, 6.00.70.a, 6.00.90.b, 6.01.10.a, 19.01.40.c, 21.00.10, 21.00.20.b, 21.10.60.b, 21.10.80.b(4), 21.11.10.a(5), 21.11.10.c(9), 21.20.10.d, 21.20.20.b(2)(a), 21.20.25.b, 21.20.70.f, 21.20.90.b-c, 21.21.10.b, 21.21.70.a(6), 21.21.70.c(10), 23.00.40.y-z, 23.00.70.h-j eff. 09/14/2015.

Rules 3.00.21, 3.00.27, 19.01.10(1), 21.00.20, 21.11.20.d, 21.20.16, 21.20.20.b.(2), 21.20.60.b, 21.20.60.e, 21.21.90.d eff. 03/16/2016.

Rules 3.00.20, 3.00.22 e, 3.00.81 g, 3.00.84, 3.01.10 d, 4.00.10, 4.00.25, 4.05.00, 5.00.15 d, 5.01.31, 6.00.20 e, 7.00.10, 8.00.10, 14.00.80 i-k, 19.01.10 b.(2), 20.00.80 a.1, 21.00.20, 21.00.30, 21.20.20 b, 27.00.00, 28.00.00 eff. 11/14/2016. Rule 10.00.51 repealed eff. 11/14/2016.

Rule 17 eff. 03/17/2017. Rule 18 repealed eff. 03/17/2017.

Rules 3.01.10 d, 7.00.30 b.4, 21.00.20, 21.00.30, 23.00.10, 23.00.70 eff. 11/14/2017. Rules 1.00.15, 5.00.55 a.(6) repealed eff. 11/14/2017.

Rules 3.05.00, 5.01.31 m, 5.01.31 r, 5.01.40 a, 5.01.50 a-f, 11.03.05, 11.04.10, 11.06.10 j, 14.02.30 d, 20.00.90 c, 20.01.00 a.2.iv, 21.00.20 d.ii, 21.20.70 g, 25.00.12 d-e, 25.00.14 c-d, 25.00.16 e eff. 09/17/2018.

Rules 1.00.24, 2.01.50, 2.01.52, 2.01.53, 2.01.56, 2.01.80, 3.00.23, 3.00.30, 3.05.10-3.05.30, 3.05.80, 7.00.30 c, 11.03.00 a, 11.07.10 a, 14.00.05 m, 14.00.40 f.1, 14.00.80 e, 15.01.11 a.(8)(i), 15.01.11 a.(9), 15.09.14 a, 19.01.10 b.-c, 23.00.10, 23.00.70, 29.00.00 eff. 11/30/2019.