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## OFFICE OF THE LIEUTENANT GOVERNOR ALASKA

#### MEMORANDUM

TO:

Amy Demboski

Department of Commerce Community and Economic Development

FROM:

April Simpson, Office of the Lieutenant Governor

465.4081

DATE:

July 31, 2020

RE:

Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy emergency regulations made permanent re: expedited handling of prescriptions in response to the COVID-19 pandemic and future disasters (12 AAC 52)

Attorney General File:

2020200314

Regulation Filed:

4/3/2020 & 7/31/2020

Effective Date:

8/30/2020

Print:

235, October 2020

cc with enclosures:

Harry Hale, Department of Law

Judy Herndon, LexisNexis

Jun Maiquis, Regulations Specialist

#### ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached fourteen pages of permanent amended emergency regulations, relating to the practice of pharmacy, including pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its May 28, 2020 teleconference meeting, under the authority of AS 08.01.075, AS 08.01.100, AS 08.80.005, AS 08.80.030, AS 08.80.110, AS 08.80.116, AS 08.80.147, AS 08.80.157, AS 08.80.159, AS 08.80.165, AS 08.80.168, AS 08.80.261, AS 08.80.295, AS 08.80.330, AS 08.80.410, AS 08.80.480, AS 11.71.900, AS 17.30.200, and AS 17.30.900, and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

On the record, in considering public comments, the Board of Pharmacy paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes described in this order take effect on the 30th day after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

Juneau, Alaska	-2
	Laura Carrillo, Executive Administrator
	Laura Carrillo, Executive Administrator
	Board of Pharmacy

FILING CERTIFICATION

April Simpson for FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that 3\ \_\_\_\_\_, 2020 at 1:13 P.m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

Kevin Meyer, Lieutenant Governor

Effective: <u>August</u> 30, <u>2020</u>.

Register: <u>235</u>, <u>0c tober</u> 2020

#### CERTIFICATION OF COMPLIANCE

I, Laura Carrillo, Executive Administrator for the Board of Pharmacy, certify that, as required by AS 44.62.260 in order to make the attached fourteen pages of regulations permanent, as of this date a legal opinion of the Department of Law has been requested under AS 44.62.060, a notice conforming to AS 44.62.200 was issued in compliance with AS 44.62.190, and an opportunity for public comment was provided under AS 44.62.210, for the following emergency regulation:

12 AAC 52.060 – 12 AAC 52.995, relating to the practice of pharmacy under the authority of AS 08.80 and 12 AAC 52, including pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions.

This regulation originally was filed as an emergency regulation on April 3, 2020.

This action is not expected to require an increased appropriation.

In considering the public comments, the Board of Pharmacy paid special attention to the cost to private persons of the regulatory action being taken.

DATE: 06/03/2020

Juneau, Alaska

Haura Carrillo, Executive Administrator Board of Pharmacy

FILING CERTIFICATION

FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on July 31, 2020 at 1:14 p.m., I filed the attached regulation according to the provisions of AS 44.62.

Register: 235, October 2010

#### FOR DELEGATION OF THE LIEUTENANT GOVERNOR'S AUTHORITY

I, KEVIN MEYER, LIEUTENANT GOVERNOR OF THE STATE OF ALASKA, designate the following state employees to perform the Administrative Procedures Act filing functions of the Office of the Lieutenant Governor:

Josh Applebee, Chief of Staff
Kady Levale, Notary Administrator
April Simpson, Regulations and Initiatives Specialist

IN TESTIMONY WHEREOF, I have signed and affixed the Seal of the State of Alaska, in Juneau, on December 11th, 2018.

OF THE STATE OF TH

KEVIN MEYER LIEUTENANT GOVERNOR

K-Men

#### Register 235, October 2020 PROFESSIONAL REGULATIONS

#### Chapter 52. Board of Pharmacy.

	(and that	subsection is furt	her unersled)
The emergene	cy adoption of 12 A	AAC 52.060(d) is made p	permanent to read: (that)
(d) In	this section, "other	r disaster" includes any d	isaster situation which causes a
pharmacy the	need to move to a	temporary location or re	sults in damage to the drug or device
inventory. (E	ff. 1/16/98, Registe	er 145; am 4/3/2020, Reg	ister 234)   i am 8 /30/2020,  Register 235
Authority:	AS 08.80.005	AS 08.80.157	AS 08.80.330 235
	AS 08.80.030		

The emergency amendment of the introductory language of 12 AAC 52.210 is made permanent to read:

12 AAC 52.210. Pharmacist duties. Except as provided in 12 AAC 52.220 and 12 AAC 52.235, the following duties may be performed only by a pharmacist:

The emergency amendment of 12 AAC 52.210(1) is made permanent to read:

receiving an oral prescription drug order from a practitioner or authorized
 a practitioner;

agent of a practitioner;

The emergency adoption of 12 ARC 52.210(8) is made permanent and that paragraph is further amended to read:

The emergency amendment of 12 AAC 52.210(6)/(7), and (8) are made permanent to read:

(6) assuming the responsibility for a filled prescription;

The emergency amendment of 12 ARC 52.210(7) is made permanent to read;

(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system; and

(8) administering

(8) administering a prescription drug order in accordance with prescriber's order.

Register 235, October 2020 PROFESSIONAL REGULATIONS (2; am 8 /30 /2020, (Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 4/3/2020, Register 234) Register 235

AS 08.80.330

The emergency repeal of 12 AAC 52.220(e)(3) is made permanent to read:

(3) repealed 4/3/2020;

AS 08.80.005

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 10/31/2019, Register 232; am 4/3/2020, Register 234)

AS 08.80.030

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.410

AS 08.80.030 AS 08.80.116

AS 08.80.116

AS 08.80.030 AS 08.80.116

AS 08.80.116

AS 08.80.410

12 ARC 52.230(c) is amended to read:

(c) Except as provided in 12 ARC

52.235, a [A] pharmacy technician may not perform any of the duties

listed in 12 ARC

The emergency amendment of 12 AAC 52.230(a)(2) is made permanent to read:

52.210.

(2) a supportive staff member assigned to work in the dispensing area of a pharmacy.

(Eff. 1/16/98, Register 145; am 4/4/2002, Register 162; am 1/23/2003, Register 165; am

4/3/2020, Register 234) am 8 130 12000 Register 235

Authority: A

Authority:

AS 08.80.030

AS 08.80.480

The emergency adoption of 12 AAC 52.235 is made permanent and that section is further amended to read:

12 AAC 52.235. Pharmacy technician with national certification. (a) A pharmacy technician who holds a national certification [AND WHO WORKS UNDER THE DIRECT and under the direct supervision of that pharmacist)

SUPERVISION OF A PHARMACIST] may, at the direction of the pharmacist on duty.

(1) perform a final check and distribute a non-controlled substance prescription if

Register 235, October 2020 PROFESSIONAL REGULATIONS

## (A) the prescription drug order has previously undergone a drug regimen review by a pharmacist, including determination in substitution;

(B) the pharmacy uses a bar code scanning and verification system that confirms the drug selected to fill the prescription is the same as indicated on the prescription label;

graphical description of the correct drug being verified; provided that if there is any destributed deviation from the image or graphical description and actual product being dispensed, a pharmacist must review and dispense the order; and

- (D) [(C)] each prescription distributed is electronically verified and the date and quantity distributed is documented in the patient record;
- (2) transfer a non-controlled substance prescription drug order as described in 12 AAC 52.500;
- (3) clarify or obtain missing information from the practitioner or the practitioner's authorized agent on a non-controlled substance prescription drug order.
- (b) Prescription drug order information clarifications under this subsection must have the following information documented on the prescription drug order
  - (1) the result of the clarification;

(2) the initials of the pharmacy technician who holds a national certification;

(3) the name of the prescriber or authorized agent they spoke to; and

(4) the date [AND TIME] of the call.

(c) A pharmacy technician who holds a national certification may not sign or initial any document that is required to be signed or initialed by a pharmacist.

DOL File#2020200314 (Adopted 5-28-2020) 3

## Register 235, October 2020 PROFESSIONAL REGULATIONS

(d) In this section, a bar code scanning and verification system" means any technology which scans the bar code on a manufacturer drug container to ensure the product being distributed matches the expectation of what was prescribed and input into the dispensing software. (Eff. 4/3/2020, Register 234; am 8 /30 / 2020, Register 235) (K Bublisher: Jo Authority: AS 08.80.005 AS 08.80.030 reflect the repeal of 12 AAC 52.300(c)(4), please insert an "and" connector at the The emergency amendment of 12 AAC 52.300(c)(3) is made permanent to read: (3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; [AND]

The emergency repeal of 12 AAC 52.300(c)(4) is made permanent to read:

(4) repealed 4/3/2020. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153;

am 5/5/2000, Register 154; am 5/26/2006, Register 178; am 4/3/2020, Register 234) Register 235

**Authority:** 

AS 08.01.100

AS 08.80.030

AS 08.80.157

AS 08.80.005

AS 08.80.147

AS 08.80.165

and that section is further amended

The emergency adoption of 12 AAC 52.446 is made permanent to read:

12 AAC 52.446. Shared pharmacy services during emergency. (a) Notwithstanding 12 AAC 52.445, during a disaster emergency declared by the governor, a pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall do so in accordance with this section.

(b) During a disaster emergency declared by the governor, a pharmacist, pharmacist intern, or pharmacy licensed or registered under AS 08.80 may participate in shared pharmacy DOL File#2020200314 (Adopted 5-28-2020) 4

Register 235, October 2020 PROFESSIONAL REGULATIONS
services as defined in 12 AAC 52.995(33) without applying for approval under 12 AAC 52.443
and 12 AAC 52.444.

- (c) Except as provided in (d) of this section, if a filling pharmacy or filling pharmacist or pharmacist intern delivers a prescription medication directly to the patient or the patient's agent, the filling pharmacy pharmacist or pharmacist intern shall provide, on the prescription container or on a separate sheet delivered with the prescription container the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist.
  - (d) The requirement of (c) of this section does not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.
  - (e) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall
  - [(1)] maintain manual or electronic records identifying, individually for each order processed, filled or dispensed
    - (A) the name, initials, or identification code of each pharmacist or pharmacist intern responsible for the final verification of dispensing; and
      (22)
      (B) the patient, date, drug, strength, directions, and quantity dispensions.
- (f) A pharmacy participating in shared pharmacy services which distributes prescription drug orders using a pharmacy technician who holds national certification shall maintain manual or electronic records identifying, individually for each order processed, filled or distributed
  - (1) the name, initials, or identification code of each pharmacy technician who holds a national certification; and
    - (2) the patient, date, drug, strength, directions, and quantity distributed.

#### Register 235, October 2020 PROFESSIONAL REGULATIONS

(g) Nothing in this section prevents a pharmacist who is employed by or working under a contract with the pharmacy, or prevents a licensed pharmacist intern or pharmacy technician from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription drug order. (Eff. 4/3/2020, Register 234)

Authority: AS 08.80.005

AS 08.80.030

The emergency repeal of 12 AAC 52.470(a) is made permanent to read:

(a) Repealed 4/3/2020.

The emergency repeal of 12 AAC 52.470(b) is made permanent to read:

(b) Repealed 4/3/2020.

The emergency amendment of 12 AAC 52.470(c) is made permanent to read:

(c) Each time a prescription drug order refill is dispensed, the pharmacist or pharmacist intern shall record the quantity and date of the dispensing.

The emergency amendment of 12 AAC 52.470(d) is made permanent to read:

- (d) A pharmacist or pharmacist intern may dispense any quantity of a prescription drug order so long as the
- (1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills; and
  - (2) drug is not a federal or state scheduled controlled substance.

Register 235, October 2020 PROFESSIONAL REGULATIONS

The emergency adoption of 12 AAC 52.470(g) is made permanent to read:

- (g) Under (d) of this section, if the total quantity of a drug or device to dispense on an existing, chronic, non-controlled substance prescription drug order has been exhausted and the pharmacist is unable to reach the practitioner, a pharmacist or pharmacist intern may continue to dispense a quantity not to exceed a 120-day supply. In this section,
- (1) "existing" means the pharmacy has record of a previous prescription drug order or the pharmacist can validate the prescription drug order from another pharmacy or patient labelled product;
- (2) "chronic" means a drug that the patient takes regularly, for greater than three months.

The emergency adoption of 12 AAC 52.470(h) is made permanent to read:

- (h) Under (g) of this section, the pharmacist must
- (1) reduce the patient's prescription drug order to a written prescription drug order using the previously verified prescription drug order information and practitioner name;
- (2) document "continuation of therapy", "COT", or words of similar meaning on the prescription drug order; and
  - (3) file and maintain the prescription in accordance with 12 AAC 52.450.

12 AAC 52.470 is amended by adding a new subsection to read:

(i) A pharmacist may not dispense a refill of a prescription drug order for a noncontrolled substance after one year from the date of issue of the original prescription drug order. (Eff. 1/16/98, Register 145; am 6/29/2018, Register 226; am 4/3/2020, Register 234; am

Register 235, October 2020 PROFESSIONAL REGULATIONS

8 /30 / 2020 , Register 235 )

**Authority:** AS 08.80.005

AS 08.80.030

The emergency amendment of 12 AAC 52.480(4) is made permanent to read:

(4) initials, which may be handwritten, of the dispensing pharmacist or pharmacist intern;

(Eff. 1/16/98, Register 145; am 1/14/2004, Register 169; am 2/15/2006, Register 177; am 4/3/2020, Register 234)

Authority:

AS 08.80.005

AS 08.80.295

AS 08.80.480

AS 08.80.030

The emergency amendment of the introductory language of 12 AAC 52.490(a) is made permanent to read:

(a) Legend drug, device, and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws. A pharmacist or pharmacist intern may dispense a prescription transmitted electronically under this section only if the prescribing practitioner includes the following information on the prescription before it is transmitted:

u ansmitteu.

(Eff. 1/16/98, Register 145; am 11/10/2001, Register 160; am 8/12/2007, Register 183; am 4/3/2020, Register 234)

**Authority:** 

AS 08.80.005

AS 08.80.030

The emergency repeal of 12 AAC 52.500(d)(1) is made permanent to read:

DOL File#2020200314 (Adopted 5-28-2020)

#### Register 235, October 2020 PROFESSIONAL REGULATIONS

(1) repealed 4/3/2020;

The emergency amendment of 12 AAC 52.500(d)(3) is made permanent to read:

- (3) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information shall record the following information:
  - (A) the name, address, and if a controlled substance, the DEA registration number of the pharmacy receiving the prescription drug order information:
  - (B) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds national certification receiving the prescription drug order information;
  - (C) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds national certification transferring the prescription drug order information; and
    - (D) the date of the transfer;

The emergency amendment of 12 AAC 52.500(d)(4) is made permanent to read:

- (4) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the transferred prescription drug order information shall record the following information:
  - (A) the original date of issue;
  - (B) the original unique identification number of the prescription;
  - (C) the quantity of drug or device remaining;

## Register 235, October 2020 PROFESSIONAL REGULATIONS

(D) the name, address, and if a controlled substance, the DEA registration number of the pharmacy transferring the prescription drug order information; and

(E) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

The emergency amendment of 12 AAC 52.500(d)(5) is made permanent to read:

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further dispensing from that prescription drug order.

The emergency amendment of 12 AAC 52.500(f)(2) is made permanent to read:

(2) to ensure that the total quantity dispensed from the prescription drug order does not exceed the total quantity authorized.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 10/31/2019, Register 232; am

4/3/2020, Register 234) (; am 8/30/200, Register 235

Authority:

AS 08.80.005

AS 08.80.030

The emergency amendment of the introductory language of 12 AAC 52.510(a) is made permanent to read:

(a) A pharmacist or pharmacist intern may dispense an equivalent drug product or interchangeable biological product instead of the prescribed drug if

(and that paragraph is further amended,

The emergency amendment of 12 AAC 52.510(a)(1) is made permanent to read:

DOL File#2020200314 (Adopted 5-28-2020) 10

#### Register 235, October 2020 PROFESSIONAL REGULATIONS

(1) the prescribing practitioner does not indicate on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary", "dispense as written", "do not substitute", or other similar wording indicating the practitioner does not want it substituted;

The emergency adoption of 12 AAC 52.510(c) is made permanent to read:

(c) Nothing in this section prohibits a patient from requesting the original trade product instead of the substituted product so long as there is nothing on the prescription drug order from d prescribing practitioner that indicates that the practitioner wants) the prescriber that would indicate they want only the substituted product dispensed. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am 4/3/2020, Register 234) (3 2m 8 /30 /200, Register 235) AS 08.80.030 AS 08.80.295 **Authority:** AS 08.80.005

(and that subsection is further amended)

The emergency amendment of 12 AAC 52.985(a) is made permanent to read:

(a) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor under AS 26.23.020 which results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

The emergency amendment of 12 AAC 52.985(b) is made permanent to read:

DOL File#2020200314 (Adopted 5-28-2020) 11

(b) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor of another state or territory, or a province of Canada which results in an individual being temporarily relocated to Alaska who is unable to refill an existing prescription,

Register 235, Outober 2020 PROFESSIONAL REGULATIONS

the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

The emergency repeal of 12 AAC 52.985(c) is made permanent to read:

(c) Repealed 4/3/2020.

The emergency repeal of 12 AAC 52.985(d) is made permanent to read:

(d) Repealed 4/3/2020.

and that subsection is further arended

The emergency adoption of 12 AAC 52.985(f) is made permanent to read:

- (f) During a disaster emergency declared by the governor of this state
- (1) a pharmacist or pharmacist intern may administer immunizations, in accordance with 12 AAC 52.992, without obtaining or maintaining a CPR certificate;
- (2) the notice required under 12 AAC 52.150(a) need not be provided until 30 days after the date the governor determines the disaster emergency no longer exists;
- (3) an application under 12 AAC 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.120, 12 AAC 52.423, 12 AAC 52.610, 12 AAC 52.696, and 12 AAC 52.697 does not need to be notarized. (Eff. 10/31/2019, Register 232; am 4/3/2020, Register 234)

**Authority:** 

AS 08.80.005

AS 08.80.030

C; am 8/31/2020, Register 235

The emergency amendment of 12 AAC 52.992(d) is made permanent to read:

(d) A pharmacist or pharmacist intern administering a vaccine must offer the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each

-DOL File#2020200314 (Adopted 5-28-2020) 12

Register <u>735</u>, <u>00000</u> 2020 **PROFESSIONAL REGULATIONS** vaccine administered.

(Eff. 7/9/2017, Register 223; am 4/3/2020, Register 234)

**Authority:** 

AS 08.01.075

AS 08.80.168

AS 08.80.480

AS 08.80.030

AS 08.80.261

The emergency amendment of 12 AAC 52.995(a)(33) is made permanent to read:

participating pharmacist, pharmacist intern, or pharmacy technician who holds a national eertification or a pharmacy of a request from another participating pharmacist, pharmacist intern, or pharmacy technician who holds a national certification or pharmacy to enter or review a prescription drug order process or fill a prescription drug order, including dispensing or distributing, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review;

The emergency adoption of 12 AAC 52.995(a)(38) is made permanent and that section is further amended to read:

(38) "pharmacy technician who holds a national certification" means a pharmacy technician, licensed by the board, who obtains and maintains an active national certification through the Pharmacy Technician Certification Board (PTCB) or the **National Healthcareer Association (NHA)** [INSTITUTE FOR THE CERTIFICATION OF PHARMACY TECHNICIANS (ICPT)].

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 11/10/2001, Register 160; am 8/21/2002, Register 163; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am DOL File#2020200314 (Adopted 5-28-2020) 13

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Register 235, October 2020 PROFESSIONAL REGULATIONS

9/11/2010, Register 195; am 12/29/2011, Register 200; am 8/1/2014, Register 211; am 6/7/2018,

Register 226; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 3 /2020,

Register 235)

Authority:

AS 08.80.005

AS 08.80.159

AS 17.30.200

AS 08.80.030

AS 11.71.900

AS 17.30.900

AS 08.80.157

## **MEMORANDUM**

## State of Alaska

Department of Law

To: The Honorable Kevin Meyer

Lieutenant Governor

Date: July 27, 2020

File No.: 2020200314

Thru: Susan R. Pollard SRP

Chief Assistant Attorney General

and Regulations Attorney

Legislation and Regulations Section

Tel. No.: 465-3600

From: Steven C. Weaver Sew

Senior Assistant Attorney General Legislation and Regulations Section Re: Board of Pharmacy emergency regulations made permanent re: expedited handling of prescriptions in response to the COVID-19 pandemic and future disasters (12 AAC 52)

The Department of Law has reviewed, against the statutory standards of the Administrative Procedure Act, the attached emergency regulations that the Board of Pharmacy intends to make permanent with further amendments. Based upon our review, and except for some of the emergency amendments to the definition of "shared pharmacy services" in 12 AAC 52.995(a), we find no legal problems. The emergency regulations were adopted on March 27, 2020, and were filed and took effect on April 3, 2020. The emergency regulations will expire on July 31, 2020 unless made permanent.

This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations. The emergency regulations were approved by the Board of Pharmacy, after the close of the public comment period, as permanent regulations with further permanent amendments. In general, the regulations are streamlining measures, to expedite the handling of prescriptions in response to the COVID-19 pandemic and future disasters, and include in particular measures to expand the involvement, within their scope practice, of pharmacist interns and of pharmacy technicians who hold certain national certifications.

We have disapproved some of the Board of Pharmacy's emergency amendments to the definition of "shared pharmacy services" in 12 AAC 52.995(a). Before those amendments, the definition of "shared pharmacy services" meant a system that applied between one participating pharmacist or pharmacy and another, and to the functions related to processing or filling a prescription drug order from the other. After the amendments the definition applied to multiple entities: (1) a participating pharmacist; (2) a pharmacist intern, presumably a "participating" one; (3) a pharmacy technician, presumably a "participating" one, who holds a national certification; or (4) a participating pharmacy. By the definition's express terms, any of these entities could

"enter or review a prescription drug order, [or] process or fill a prescription drug order, including dispensing or distributing, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review[.]"

Perhaps the Board of Pharmacy meant to link the definition to 12 AAC 52.446: the new section, adopted by emergency action, to address shared pharmacy services during a disaster emergency declared by the governor. But in that case, the amendments to the definition raise technical issues. First, the definition by its terms applies across 12 AAC 52, but is no longer in full harmony with 12 AAC 52.445, the existing section that addresses shared pharmacy services in times other than disaster emergencies. Second, even 12 AAC 52.446 appears on its face to recognize the statutory limits on the roles of the pharmacist intern and the pharmacy technician. For example, a pharmacist intern does not act independently of a pharmacy, and a pharmacy technician distributes (noncontrolled) prescription drug orders, rather than dispensing them. *See* 12 AAC 52.446(e) and (f); *see also* the definitions of "dispense" and "distribute" in AS 08.80.480. Certainly from a grammatical perspective, the definition of "shared pharmacy services" now packs too much material in one paragraph.

Perhaps also the Board of Pharmacy intended the edits to the definition of "shared pharmacy services" to describe the system that allows the processing by a participating entity of a request from another participating entity. The "shared pharmacy services" actually constitute the system--for example, a pharmacist's or pharmacy's technology or method--that allows the listed individuals or entities to send and receive the data necessary to perform the listed tasks, and not actually to perform those tasks. But after discussions with the agency, our understanding is that instead of referring to the processing system alone for listed individuals to transmit data, the Board of Pharmacy meant to expand who could perform the listed tasks.

This reading of the proposed amendments to "shared pharmacy services" could allow, at a minimum, pharmacy technicians to dispense prescribed drugs or substantively counsel patients, acts that are part of the practice of pharmacy under AS 08.80.480, pharmacy technicians to perform tasks without immediate supervision, and pharmacist interns to engage in the practice of pharmacy independently of a pharmacy. Accordingly, we have retained the additional tasks named as part of "shared pharmacy services," but we have marked for disapproval amendments that would expand the list of persons who could perform those activities. *See* the definitions of "dispense," "intern," "pharmacy technician," and "practice of pharmacy" in AS 08.80.480 and the definitions of "direct supervision" and "personal supervision" in 12 AAC 52.995(a); *see also* 12 AAC 52.230(b). Please consult the Department of Law if you need additional advice on how to proceed.

The April 3, 2020 certification of adoption order, the April 7, 2020 public notice, the June 3, 2020 certification of compliance, and the June 3, 2020 certification of adoption order all state that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

We have made some technical corrections to conform the regulations in accordance with AS 44.62.125. The corrections are shown on the attached copy of the regulations.

#### **SCW**

cc w/enc:

Richard Holt, D.Ph., Chair

Board of Pharmacy

(via e-mail through Jun Maiquis)

Amy Demboski, Regulations Contact

Department of Commerce, Community, and Economic Development

Sara Chambers, Director

Division of Corporations, Business, and Professional Licensing

Department of Commerce, Community, and Economic Development

Laura Carrillo, Executive Administrator

Division of Corporations, Business, and Professional Licensing

Department of Commerce, Community, and Economic Development

Jun Maiquis, Regulations Specialist

Division of Corporations, Business, and Professional Licensing

Department of Commerce, Community, and Economic Development

Megyn Weigand, Assistant Attorney General

Commercial, Fair Business, and Child Support Section

#### AFFIDAVIT OF BOARD ACTION

I, Laura Carrillo, Executive Administrator for the Board of Pharmacy, being duly sworn, state the following:

The attached motion dealing with pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions was passed by the Board of Pharmacy during its May 28, 2020 teleconference meeting.

Date: 06/03/2020 Juneau, Alaska

Laura Carrillo, Executive Administrator

WORN TO before me this  $\frac{3}{2}$  day of SUBSCRIBED

Notary Public in and for the

State of Alaska

My commission expires:

Excerpt from the Draft Minutes of the May 28, 2020 Teleconference Meeting of the Alaska Board of Pharmacy

#### Emergency regulations 12 AAC 52.060 – 12 AAC 52.995

In considering the emergency regulations project being made permanent, the Board reviewed and considered public comments received.

The Board does not expect the regulations change to incur cost to private persons, or to require an increased appropriation.

On a motion duly made by Rich Holt and seconded by Lana Bell to adopt the following emergency regulations as written and publicly noticed:

12 AAC 52.060(d), 12 AAC 52.210, 12 AAC 52.220(e)(3), 12 AAC 52.230(a)(2), 12 AAC 52.300(c)(3),

12 AAC 52.300(c)(4), 12 AAC 52.446, 12 AAC 52.470(a), 12 AAC 52.470(b), 12 AAC 52.470(c),

12 AAC 52.470(d), 12 AAC 52.470(g), 12 AAC 52.470(h), 12 AAC 52.480(4), 12 AAC 52.490(a),

12 AAC 52.500(d)(1), 12 AAC 52.500(d)(3), 12 AAC 52.500(d)(4), 12 AAC 52.500(d)(5),

12 AAC 52.500(f)(2), 12 AAC 52.510(a), 12 AAC 52.510(a)(1), 12 AAC 52.510(c), 12 AAC 52.985(a),

12 AAC 52.985(b), 12 AAC 52.985(c), 12 AAC 52.985(d), 12 AAC 52.985(f), 12 AAC 52.992(d),

12 AAC 52.995(a)(33);

And to adopt the following emergency regulations as further amended:

12 AAC 52.235 and 12 AAC 52.995(a)(38);

And to adopt a new subsection in 12 AAC 52.470(i); it was:

RESOLVED to adopt the aforementioned emergency regulations as permanent, including those requiring further amendments and adding a new subsection.

	APPROVE	<b>DENY ABSTAIN</b>	ABSENT
Leif Holm	x		
Richard Holt	x		
Justin Ruffridge	x		
Lana Bell	x		
Tammy Lindemuth	x		
James Henderson	x		
Sharon Long			x

The motion passed with no further discussion.

## NOTICE OF ADOPTION OF EMERGENCY REGULATION TO THE PRACTICE OF PHARMACY IN THE REGULATIONS OF THE BOARD OF PHARMACY

BRIEF DESCRIPTION: The Board of Pharmacy proposes to make permanent regulation changes made by emergency regulation relating to the practice of pharmacy under the authority of AS 08.80 and 12 AAC 52, including pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions.

On March 27, 2020, the Board of Pharmacy (Board) adopted, as an emergency regulation, changes in Title 12, Chapter 52, of the Alaska Administrative Code including the following:

- 12 AAC 52.060. Fire or other disaster, is proposed to establish a definition for "other disaster"; to
  include any disaster which causes a pharmacy to move to a temporary location or results in damage
  to the drug or device inventory.
- 2. 12 AAC 52.210. Pharmacist duties, is proposed to add receiving an oral prescription drug order from a practitioner or authorized agent of a practitioner, and to also add administer a prescription drug order in accordance with the prescriber's order.
- 3. 12 AAC 52.220. Pharmacist interns, is proposed to remove the requirement to physically review prescription drug orders and dispensed products before distributing to a patient or the patient's agent.
- 4. 12 AAC 52.230. Pharmacy technicians, is proposed to remove cashier or bookkeeper from having to obtain a license as a pharmacy technician.
- 5. 12 AAC 52.235. Pharmacy technician with national certification, is a proposed new section that provides additional scope to pharmacy technicians who holds a national certification; allows them to perform final checks on non-controlled substance prescriptions, transfer non-controlled substance prescription orders, clarify or obtain missing information from practitioner for non-controlled substance prescriptions.
- 6. 12 AAC 52.300. License renewal, is proposed to remove the requirement to submit documentation of continuing education and accept attestation of completing said continuing education requirements, to suspend CPR certification requirements, and to remove the jurisprudence questionnaire requirement for renewal.
- 7. 12 AAC 52.446. Shared pharmacy services during emergency, is a proposed new section that establishes shared pharmacy services during an emergency; it suspends the existing shared pharmacy regulations in 12 AAC 52.445 only during the duration of an emergency; allows a pharmacist intern and pharmacy technician to engage in shared pharmacy services; removes requirements for shared pharmacy services to be approved by the board.
- 8. **12 AAC 52.470. Refills,** is proposed to amend the provisions related to refills, including the ability to dispense up to a 120-day supply.
- 9. 12 AAC 52.480. Labeling, is proposed to clarify that initials may be handwritten on the prescription label.
- 10. 12 AAC 52.490. Prescriptions by electronic transmission, is proposed to clarify that prescriptions for devices may be transmitted electronically.
- 11. 12 AAC 52.500. Transfer of a prescription drug order, is proposed to allow pharmacist interns and pharmacy technicians who holds a national certification to engage in the transfer of a prescription drug order; specifies what conditions must be met in order to engage in related

activities.

- 12. 12 AAC 52.510. Substitution, is proposed to clarify that a prescriber can indicate on the prescription whether a substitution for an equivalent drug interchangeable can be dispensed; provides for a patient to request the original drug product provided the prescriber has not indicated this cannot be provided.
- 13. 12 AAC 52.985. Emergency preparedness, is proposed to amend the provisions related to emergency preparedness; removes section on supply day and refills; waives notary requirements for application.
- 14. 12 AAC 52.992. Independent administration of vaccines and related emergency medications, is proposed to add pharmacist interns to require them to offer current vaccine information statements for administration.
- 15. **12 AAC 52.995. Definitions**, is proposed to update the definition for "shared pharmacy services" and establish a definition for "pharmacy technician who holds a national certification".

The emergency regulations took effect on April 3, 2020, and will expire July 31, 2020. The Board intends to make the emergency regulations permanent.

You may comment on the regulation changes, including the potential costs to private persons of complying with the changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/197699, and using the comment link. The comments must be received not later than 4:30 p.m. on May 15, 2020. Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. The questions must be received at least 10 days before the end of the public comment period. The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than May 8, 2020 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-EmergencyRegs-0420.pdf.

The language of the permanent regulation may be different from that of the original emergency regulation and may include other provisions dealing with the same subject. You should comment during the time allowed if your interests could be affected. Written comments and questions received are public records and are subject to public inspection.

**Statutory Authority:** AS 08.01.075; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.110; AS 08.80.116; AS 08.80.147; AS 08.80.157; AS 08.80.159; AS 08.80.165; AS 08.80.168; AS 08.80.261; AS 08.80.295; AS 08.80.330; AS 08.80.410; AS 08.80.480; AS 11.71.900; AS 17.30.200; AS 17.30.900 **Statutes Being Implemented, Interpreted, or Made Specific:** AS 08.01.075; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.110; AS 08.80.116; AS 08.80.147; AS 08.80.157; AS 08.80.159; AS

08.80.165; AS 08.80.168; AS 08.80.261; AS 08.80.295; AS 08.80.330; AS 08.80.410; AS 08.80.480; AS 11.71.900; AS 17.30.200; AS 17.30.900

Fiscal Information: The proposed regulation changes are not expected to require an increased appropriation.

DATE: 4/6/2020

Jun Maiquis, Regulations Specialist Division of Corporations, Business and

Professional Licensing

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

## ADDITIONAL REGULATION NOTICE INFORMATION (AS 44.62.190(d))

- 1. Adopting agency: Board of Pharmacy Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.
- 2. General subject of regulation: Pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions.
- 3. Citation of regulation: 12 AAC 52.060 12 AAC 52.995.
- 4. Department of Law file number: 2020200314.
- 5. Reason for the proposed action: Emergency regulations.
- 6. Appropriation/Allocation: Corporations, Business and Professional Licensing #2360.
- 7. Estimated annual cost to comply with the proposed action to:

A private person: None known.

Another state agency: None known.

A municipality: None known.

- 8. Cost of implementation to the state agency and available funding (in thousands of dollars): No costs are expected in FY 2020 or in subsequent years.
- 9. The name of the contact person for the regulation:

Laura Carrillo, Executive Administrator

Alaska Board of Pharmacy

Division of Corporations, Business and Professional Licensing

Department of Commerce, Community, and Economic Development

Telephone: (907) 465-1073

E-mail: laura.carrillo@alaska.gov

10. The origin of the proposed action: Board of Pharmacy.

11. Date: 4/6/2020

Prepared by:

Regulations Specialist

# ANCHORAGE DAILY NEWS AFFIDAVIT OF PUBLICATION

Account #: 268972 ST OF AK/DEC/OCCU Attention To: ATTN TO: JUN MAIQUIS PO BOX 110806, JUNEAU, AK 99811

Order #: W0014343

RECEIVED Juneau

APR 2 0 2020

**CBPL** 

#### STATE OF ALASKA THIRD JUDICIAL DISTRICT

Lisi Misa being first duly sworn on oath deposes and says that she is a representative of the Anchorage Daily News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

04/07/2020

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate charged private individuals.

Signed

Subscribed and sworn to before me this 13th day of April 2020.

Notary Public in and for The State of Alaska.

Third Division

Anchorage, Alaska

MY COMMISSION EXPIRES

Cost: \$771.94

#### AFFIDAVIT OF NOTICE OF ADOPTION OF EMERGENCY REGULATION AND FURNISHING OF ADDITIONAL INFORMATION

I, Jun Maiquis, Regulations Specialist, of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being sworn, state the following:

As required by AS 44.62.250, notice of the April 3, 2020 emergency changes to 12 AAC 52.060 through 12 AAC 52.995, dealing with pharmacist duties, interns, technician with national certification, renewal, shared pharmacy services during emergency, prescriptions, emergency preparedness, and definitions, has been given under AS 44.62.190(a) by being

- 1. published in a newspaper or trade publication;
- 2. furnished to every person who has filed a request for notice of proposed action with the state agency;
- 3. furnished to appropriate state officials:
- furnished to interested persons;
- 5. furnished to the Department of Law, along with a copy of the regulation:
- electronically transmitted to incumbent State of Alaska legislators:
- posted on the Alaska Online Public Notice System: as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1).

As required by AS 44.62.190, additional regulation notice information regarding the April 3, 2020 emergency changes to the regulation described above has been furnished to interested persons and furnished to those in (2), (4) and (6) of the list above. The additional regulation notice information also has been posted on the Alaska Online Public Notice System.

DATE: uneau, Alaska

Regulations Specialist

SUBSCRIBED AND SWORN TO before me this

semA al

Notary Public in and for the

State of Alaska

My commission expires:

#### AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Jun Maiquis, Regulations Specialist for the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being duly sworn, state the following:

In compliance with AS 44.62.215, the Board of Pharmacy has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Board of Pharmacy emergency regulations on dealing with pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions.

DATE:	6/3	2020	
	Juneau	Alaska	

Jun Maiguis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 3 day of June, 2020.

NOTARY

otary Public in and for the

State of Alaska

My commission expires: w