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OFFICE OF THE LIEUTENANT GOVERNOR
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MEMORANDUM

TO: Jun Maiquis
Department of Commerce, Community & Economic Development

FROM: Scott Meriwether, Office of the Lieutenant Governor
465.4081

DATE: June 9, 2017

RE: Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy regulations re: pharmacist interns, prescription drug order records, facility standards, patient counseling, and administration of vaccines or related emergency medication (12 AAC 52.120(b)(3)(A); 12 AAC 52.210(1); 12 AAC 52.320(e); 12 AAC 52.400; 12 AAC 52.450; 12 AAC 52.460(a)(9)-(11); 12 AAC 52.500; 12 AAC 52.585(a); 12 AAC 52.992)

Attorney General File:	JU2017200015
Regulation Filed:	6/9/2017
Effective Date:	7/9/2017
Print:	223, October 2017

cc with enclosures: Linda Miller, Department of Law
Judy Herndon, LexisNexis

ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached nine pages of regulations, dealing with requirements for a pharmacy intern license, pharmacist duties, continuing education requirements for a pharmacist administering vaccines or related emergency medications, general guidelines for pharmacies, prescription drug order records and information, transfer of a prescription drug order, mandatory patient counseling, and establishing standards for the independent administration of vaccines and related emergency medications, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its March 2-3, 2017 teleconference meeting, under the authority of AS 08.01.075, 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 08.80.165, AS 08.80.168, AS 08.80.261, AS 08.80.330, and AS 08.80.480 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.

DATE: March 3rd 2017
North Pole, Alaska

Leif Holm, PharmD., Chairman
Board of Pharmacy

FILING CERTIFICATION

I, Byron Mallott, Lieutenant Governor for the State of Alaska, certify that on June 9, 2017 at 1:40 p.m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

Byron Mallott, Lieutenant Governor

Effective: July 9, 2017.
Register: 223, October 2017

Chapter 52. Board of Pharmacy.

12 AAC 52.120(b)(3)(A) is amended to read:

(A) **enrolled** [COMPLETED THE FIRST YEAR OF A PROFESSIONAL PHARMACY CURRICULUM] in a college of pharmacy accredited by the ACPE; or

(Eff. 1/16/98, Register 145; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am 11/16/2012, Register 204; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116 AS 08.80.030

12 AAC 52.210(1) is amended to read:

(1) receiving an oral prescription drug order [, INCLUDING REFILL APPROVAL OR DENIAL THAT INCLUDES ANY CHANGE TO THE ORIGINAL PRESCRIPTION DRUG ORDER];

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

12 AAC 52.320 is amended by adding a new subsection to read:

(e) A pharmacist administering a vaccine or related emergency medication under 12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations or vaccines as part of the 30 contact hours of continuing education required under (a) of this section. (Eff. 1/16/98,

Register 145; am 5/5/2000, Register 154; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165

AS 08.80.030

12 AAC 52.400 is amended to read:

12 AAC 52.400. General guidelines for pharmacies. A person that is required to be licensed by AS 08.80 and who has a license under AS 08.80 and this chapter shall adhere to the guidelines on facilities, reference material, equipment, supplies, and other guidelines established by the board in the pamphlet titled, *"Facility Standards for Pharmacies,"* dated **November 2016** [FEBRUARY 2008], and incorporated by reference in this section. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.400, *"Facility Standards for Pharmacies"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

(A Publisher: Please delete the 2nd paragraph of the editor's note that follows 12 AAC 52.400.)

12 AAC 52.450 is amended to read:

12 AAC 52.450. Prescription drug order records. (a) A pharmacy shall maintain prescription drug orders for a period of two years from the date of filling or the date of the last dispensed refill. The prescription drug orders shall be maintained [IN NUMERICAL ORDER AND] in a manner that ensures they will remain legible for the required two-year period.

(b) To comply with (a) of this section, a pharmacy shall maintain the prescription drug

orders by [KEEPING IN ITS FILE]

(1) **keeping** the original **hard copy** [WRITTEN] prescription drug order **presented by a patient**;

(2) **keeping** a plain paper version of the prescription drug order received by facsimile or digital electronic transmittal; [OR]

(3) **keeping** a prescription drug order put into writing either manually or electronically by the pharmacist**; or**

(4) electronically storing and maintaining the prescription drug order in a readily retrievable format. (Eff. 1/16/98, Register 145; am 11/10/2001, Register 160; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

(9)

12 AAC 52.460(a) is amended to read:

(a) ~~Before a pharmacist may fill a prescription drug order, the pharmacist shall obtain the following information:~~

(9) if a written **or hard copy** prescription drug order, the prescribing practitioner's **handwritten, digital, electronic, or stamped** signature; [AND]

12 AAC 52.460(a)(10) is amended to read:

(10) if a [FACSIMILE] prescription drug order **is received by the pharmacy as a facsimile**, the prescribing practitioner's **handwritten, digital, electronic, or stamped** signature, or authorized agent's signature**; and**

12 AAC 52.460(a) is amended by adding a new paragraph to read:

(11) if the prescription drug order is signed by an authorized agent, it must include the name of the prescribing practitioner.

(Eff. 1/16/98, Register 145; am 9/11/2010, Register 195; am 9/17/2011, Register 199; am

11/16/2012, Register 204; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.500(b) is amended to read:

(b) Original prescription drug order information for controlled substances listed in schedules III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner. **The transfer must be communicated directly between two licensed pharmacists.**

12 AAC 52.500(c) is amended to read:

(c) Original prescription drug order information for noncontrolled substances may be transferred **verbally, electronically, or ~~via~~ facsimile** (by means of) between pharmacies without limitation up to the number of originally authorized refills.

12 AAC 52.500(d) is amended to read:

(d) A pharmacy transferring a prescription drug order or receiving a transferred prescription drug order must meet the following requirements:

(1) **if transferred verbally,** the transfer shall be communicated directly between two licensed pharmacists;

(2) both the original and the transferred prescription drug order must meet the requirements of 12 AAC 52.450(a);

(3) the pharmacist transferring the prescription drug order information shall

[(A) **repealed / /**]WRITE "VOID" ON THE FACE OF THE TRANSFERRED PRESCRIPTION DRUG ORDER; AND

(B) record [ON THE REVERSE SIDE OF THE TRANSFERRED PRESCRIPTION DRUG ORDER] the following information:

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

(ii) the name of the pharmacist receiving the prescription drug order information;

(iii) the name of the pharmacist transferring the prescription drug order information; and

(iv) the date of the transfer;

(4) the pharmacist receiving the transferred prescription drug order information shall

[(A) ~~repealed~~] WRITE "TRANSFER" ON THE FACE OF THE TRANSFERRED PRESCRIPTION DRUG ORDER; AND

(B) record [ON THE TRANSFERRED PRESCRIPTION DRUG ORDER] the following information:

(i) the original date of issue and date of dispensing, if different from the date of issue;

(ii) the original prescription drug order number and the number of refills authorized on the original prescription drug order;

(iii) the number of valid refills remaining and the date of the last refill;

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

(v) the name of the pharmacist transferring the prescription drug order information; and

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

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030

The introductory language of 12 AAC 52.585(a) is repealed and readopted to read:

(a) Before dispensing a prescription for the first time for a new patient of the pharmacy, ~~or~~ a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, the pharmacist or pharmacy intern providing prescription services ~~must~~ shall personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

. . .

(Eff. 1/16/98, Register 145; am 5/15/2004, Register 170; am 7/9/2017, Register 223)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52 is amended by adding a new section to read:

12 AAC 52.992. Independent administration of vaccines and related emergency medications. (a) Before a pharmacist may independently administer a human vaccine or related emergency medication to a patient who does not have immunization contraindications as listed by the CDC, FDA, or manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist ~~must~~

(1) must successfully complete a course accredited by the Accreditation Council for Pharmacy Education (ACPE) or a comparable course for pediatric, adolescent, and adult immunization practices that includes instruction on

(A) basic immunology, vaccine, and immunization protection;

(B) diseases that may be prevented by vaccination or immunization;

(C) current ~~Centers for Disease Control and Prevention~~ (CDC) immunization schedules;

(D) vaccine storage and management;

(E) informed consent;

(F) physiology and techniques for administration of immunizations;

(G) pre-immunization and post-immunization assessment and counseling;

(H) immunization reporting and records management; and

(I) identifying, responding to, documenting, and reporting adverse responses;

(2) must maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external ~~electronic~~ defibrillator (AED) training; ~~and~~

(3) ~~a pharmacist~~ who has not administered a vaccine ~~within~~ during the past 10 years must complete a course as described in ~~(a)~~(1) of this sub. section before administering a vaccine; and

(4) ~~pharmacist~~ must adhere to 12 AAC 52.320 continuing education requirements, including under 12 AAC 52.320(e).

(b) A pharmacy from which a pharmacist administers a human vaccine or related emergency medication under this section

(1) must stock the following emergency medications in an emergency medication kit ~~which~~ that is separate from the regular dispensing inventory, and ~~which~~ that is carried by the pharmacist if providing off-site immunizations:

(A) oral and injectable diphenhydramine; and

(B) adult and pediatric auto-inject epinephrine device, or injectable epinephrine;

(2) must maintain a policy and procedure manual detailing the immunization practices that must be followed ~~and which:~~

(A) designates either the pharmacist-in-charge ~~(PIC)~~ or an assigned vaccine coordinator who will be responsible for maintaining the policy and procedures manual;

(B) documents that the policy and procedures manual has been reviewed and updated annually;

(C) addresses how vaccine related adverse reactions are to be reported to the Vaccine Adverse Event Reporting System (VAERS);

(D) addresses proper vaccine storage, handling, and maintenance, including maintaining manufacturer-recommended temperatures during transportation of vaccines;

(E) addresses proper disposal of used or contaminated supplies;

(F) contains a written emergency protocol for handling accidental needlesticks and adverse reactions including the administration of emergency ~~related~~ medications; and

(G) details how records must be kept;

(3) must have access to the latest edition of the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* as a reference; and

(4) must display each pharmacist's certification of completing the immunization course described in this section.

(c) Before administering an immunization or related emergency medication, a pharmacy intern ~~shall~~ must

(1) have completed an ACPE ~~approved~~ C-accredited immunization course or other comparable course that meets the requirements of (a)(1) of this section;

(2) maintain certification ~~at completing an~~ and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) ~~program~~ and automated ~~electronic~~ external defibrillator (AED) training; and

(3) be under the direct supervision of a pharmacist who has met the requirements of this chapter.

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

(e) A pharmacist or intern independently administering a vaccine must comply with 7 AAC 27.650.

For purposes of this section, a pharmacist independently administers a human vaccine or related emergency medication if ¶ (1) the

(f) ~~"Independent administration" means a~~ pharmacist meets the requirements of this chapter is the prescriber and administrator of the vaccine, or ¶ (2) a pharmacist ~~if an~~ intern meeting the requirements of this chapter ~~is~~ administering the vaccine, and the pharmacist supervising the intern is the prescriber.

(g) Failure to comply with this section constitutes unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075. (Eff. 7/9/2017, Register 223)

Authority: AS 08.01.075 AS 08.80.168 AS 08.80.480
AS 08.80.030 AS 08.80.261

¶ (h) In this section,
(1) "CDC" means the United States Department of Health and Human Services, Centers For Disease Control and Prevention;
(2) "FDA" means the United States Food and Drug Administration.