| | INSULIN ACCESS AMENDMEN IS |
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| | 2020 GENERAL SESSION |
| | STATE OF UTAH |
| | Chief Sponsor: Norman K. Thurston |
| | Senate Sponsor: |
| LONG TIT | TLE |
| General De | escription: |
| This | s bill creates mechanisms to increase Utahns' access to affordable insulin. |
| Highlighte | d Provisions: |
| This | s bill: |
| • | creates an incentive for health benefit plans to reduce the required copayments for |
| insulin; | |
| • | creates an incentive for the Public Employees' Benefit and Insurance Program to |
| reduce requ | ired copayments for insulin; |
| • | directs the Public Employees' Benefit and Insurance Program to purchase insulin at |
| discounted | prices and to create a program that allows public employees to access the |
| discounted | insulin; |
| • | increases the number of days for which an insulin prescription can be refilled; |
| • | increases the length of time an insulin prescription can last; |
| • | increases the number of professions that can be licensed to prescribe insulin; and |
| • | makes technical changes. |
| Money App | propriated in this Bill: |
| Non | e e |
| Other Spec | rial Clauses: |
| This | s bill provides a special effective date. |
| Utah Code | Sections Affected: |



| AM | IENDS: |
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| | 31A-22-626, as last amended by Laws of Utah 2015, Chapter 258 |
| | 58-17b-102, as last amended by Laws of Utah 2019, Chapter 343 |
| | 58-17b-501, as last amended by Laws of Utah 2018, Chapter 295 |
| | 58-17b-609, as last amended by Laws of Utah 2005, Chapter 160 |
| | 58-17b-612, as last amended by Laws of Utah 2019, Chapter 343 |
| | 58-17b-625, as last amended by Laws of Utah 2019, Chapter 343 |
| | 58-31b-102, as last amended by Laws of Utah 2019, Chapter 233 |
| | 58-31b-803, as last amended by Laws of Utah 2019, Chapter 233 |
| | 62A-4a-213, as last amended by Laws of Utah 2019, Chapter 257 |
| EN. | ACTS: |
| | 26-67-101 , Utah Code Annotated 1953 |
| | 26-67-102 , Utah Code Annotated 1953 |
| | 26-67-103 , Utah Code Annotated 1953 |
| | 26-67-104 , Utah Code Annotated 1953 |
| | 26-67-105 , Utah Code Annotated 1953 |
| | 49-20-420, Utah Code Annotated 1953 |
| | 49-20-421, Utah Code Annotated 1953 |
| | 58-17b-608.2 , Utah Code Annotated 1953 |
| Ве | it enacted by the Legislature of the state of Utah: |
| | Section 1. Section 26-67-101 is enacted to read: |
| | CHAPTER 67. INSULIN ACCESS ACT |
| | <u>26-67-101.</u> Title. |
| | This chapter is known as the "Insulin Access Act." |
| | Section 2. Section 26-67-102 is enacted to read: |
| | 26-67-102. Definitions. |
| | As used in this chapter: |
| | (1) "Division" means the Division of Occupational and Professional Licensing created |
| in S | Section 58-1-103. |
| | (2) "Insulin" means the same as that term is defined in Section 49-20-421. |

| 59 | (3) "Local health department" means: |
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| 60 | (a) a local health department, as defined in Section 26A-1-102; or |
| 61 | (b) a multicounty local health department, as defined in Section 26A-1-102. |
| 62 | (4) "Patient counseling" means the same as that term is defined in Section 58-17b-102. |
| 63 | (5) "Pharmacist" means the same as that term is defined in Section 58-17b-102. |
| 64 | (6) "Pharmacy intern" means the same as that term is defined in Section 58-17b-102. |
| 65 | (7) "Physician" means the same as that term is defined in Section 26-2-2. |
| 66 | (8) "Practice of registered nursing" means the same as that term is defined in Section |
| 67 | <u>58-31b-102.</u> |
| 68 | (9) "Prescribe" means the same as that term is defined in Section 58-17b-102. |
| 69 | (10) "Registered nurse" means a person licensed under Title 58, Chapter 31b, Nurse |
| 70 | Practice Act, to engage in the practice of registered nursing. |
| 71 | Section 3. Section 26-67-103 is enacted to read: |
| 72 | 26-67-103. Duty or standard of care. |
| 73 | This chapter does not create a duty or standard of care for a person to prescribe insulin. |
| 74 | Section 4. Section 26-67-104 is enacted to read: |
| 75 | 26-67-104. Authorization to prescribe insulin. |
| 76 | (1) Notwithstanding Title 58, Chapter 17b, Pharmacy Practice Act, a person licensed |
| 77 | under Title 58, Chapter 17b, Pharmacy Practice Act, to prescribe insulin may prescribe insulin |
| 78 | to a patient: |
| 79 | (a) (i) if the insulin is insulin on which the patient is currently stable; or |
| 80 | (ii) if the insulin is insulin that, in the professional judgment of the pharmacist, is |
| 81 | compatible with insulin on which the patient is currently stable; |
| 82 | (b) without any other prescription drug order from a person licensed to prescribe |
| 83 | insulin; and |
| 84 | (c) in accordance with the guidelines in Section 26-67-105. |
| 85 | (2) Notwithstanding Title 58, Chapter 31b, Nurse Practice Act, a registered nurse |
| 86 | licensed under Title 58, Chapter 31b, Nurse Practice Act, may prescribe insulin to a patient: |
| 87 | (a) (i) if the insulin is insulin on which the patient is currently stable; or |
| 88 | (ii) if the insulin is insulin that, in the professional judgment of the registered nurse, is |
| 89 | compatible with insulin on which the patient is currently stable; |

| 90 | (b) without any other prescription drug order from a person licensed to prescribe |
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| 91 | insulin; and |
| 92 | (c) in accordance with the guidelines in Section 26-67-105. |
| 93 | Section 5. Section 26-67-105 is enacted to read: |
| 94 | 26-67-105. Guidelines for prescribing insulin. |
| 95 | (1) Before prescribing insulin under this chapter, a pharmacist, pharmacy intern, or |
| 96 | registered nurse: |
| 97 | (a) shall obtain a completed self-screen risk assessment, that has been approved by the |
| 98 | division in collaboration with the Board of Pharmacy, the Board of Nursing, and the Physicians |
| 99 | Licensing Board, from the patient before prescribing the insulin; |
| 100 | (b) if the results of the evaluation described in Subsection (1)(a) indicate that it is |
| 101 | unsafe to prescribe the insulin to a patient: |
| 102 | (i) may not prescribe insulin to the patient; and |
| 103 | (ii) shall refer the patient to a physician; |
| 104 | (c) may not continue to prescribe insulin to a patient for more than 12 months after the |
| 105 | date of the initial prescription without evidence that the patient has consulted with a primary |
| 106 | care physician or a specialist trained in the treatment of diabetes during the proceeding 12 |
| 107 | months; and |
| 108 | (d) shall provide the patient with: |
| 109 | (i) written information regarding the importance of seeing the patient's primary care |
| 110 | physician to obtain recommended tests and screening; and |
| 111 | (ii) a copy of the record of the encounter with the patient that includes: |
| 112 | (A) the patient's completed self-assessment; and |
| 113 | (B) a description of the insulin prescribed or the basis for not prescribing insulin. |
| 114 | (2) If a pharmacist, pharmacy intern, or registered nurse prescribes insulin to a patient, |
| 115 | the pharmacist, pharmacy intern, or registered nurse shall, at a minimum, provide patient |
| 116 | counseling to the patient regarding: |
| 117 | (a) the appropriate administration and storage of the insulin; |
| 118 | (b) the need for regular checkups with a primary care physician; and |
| 119 | (c) the risks associated with not administering the insulin correctly. |
| 120 | (3) The division, in collaboration with the Board of Pharmacy, the Board of Nursing, |

| 121 | and the Physicians Licensing Board, shall make rules in accordance with Title 63G, Chapter 3, |
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| 122 | Utah Administrative Rulemaking Act, establishing the self-screening risk assessment described |
| 123 | in Subsection (1)(a). |
| 124 | Section 6. Section 31A-22-626 is amended to read: |
| 125 | 31A-22-626. Coverage of diabetes. |
| 126 | (1) As used in this section, ["diabetes"]: |
| 127 | (a) "Diabetes" includes individuals with: |
| 128 | [(a)] (i) complete insulin deficiency or type 1 diabetes; |
| 129 | [(b)] (ii) insulin resistant with partial insulin deficiency or type 2 diabetes; [and] or |
| 130 | [(c)] (iii) elevated blood glucose levels induced by pregnancy or gestational diabetes. |
| 131 | (b) "Lowest tier" means the lowest copayment tier of a health benefit plan or the |
| 132 | preventive drug tier of a high deductible health plan. |
| 133 | (2) The commissioner shall establish, by rule, minimum standards of coverage for |
| 134 | diabetes for accident and health insurance policies that provide a health insurance benefit |
| 135 | before July 1, 2000. |
| 136 | (3) In making rules under Subsection (2), the commissioner shall require rules: |
| 137 | (a) with durational limits, amount limits, deductibles, and coinsurance for the treatment |
| 138 | of diabetes equitable or identical to coverage provided for the treatment of other illnesses or |
| 139 | diseases; and |
| 140 | (b) that provide coverage for: |
| 141 | (i) diabetes self-management training and patient management, including medical |
| 142 | nutrition therapy as defined by rule, provided by an accredited or certified program and referred |
| 143 | by an attending physician within the plan and consistent with the health plan provisions for |
| 144 | self-management education: |
| 145 | (A) recognized by the federal Centers for Medicare and Medicaid Services; or |
| 146 | (B) certified by the Department of Health; and |
| 147 | (ii) the following equipment, supplies, and appliances to treat diabetes when medically |
| 148 | necessary: |
| 149 | (A) blood glucose monitors, including those for the legally blind; |
| 150 | (B) test strips for blood glucose monitors; |
| 151 | (C) visual reading urine and ketone strips; |

| 152 | (D) lancets and lancet devices; |
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| 153 | (E) insulin; |
| 154 | (F) injection aides, including those adaptable to meet the needs of the legally blind, and |
| 155 | infusion delivery systems; |
| 156 | (G) syringes; |
| 157 | (H) prescriptive oral agents for controlling blood glucose levels; and |
| 158 | (I) glucagon kits. |
| 159 | (4) Beginning January 1, 2021, a health benefit plan that provides coverage for insulin |
| 160 | shall: |
| 161 | (a) cap the total amount that an insured is required to pay for insulin at an amount not |
| 162 | to exceed \$30 per 30-day supply of insulin, regardless of the amount or type of insulin needed |
| 163 | to fill the insured's prescription; and |
| 164 | (b) apply the cap to an insured regardless of whether the insured has met the plan's |
| 165 | deductible. |
| 166 | (5) Subsection (4) does not apply to a health plan that: |
| 167 | (a) covers insulin under the lowest tier of drugs; and |
| 168 | (b) does not require an insured to meet a deductible before the plan will cover insulin |
| 169 | at the lowest tier. |
| 170 | (6) A health benefit plan shall reimburse an insured for insulin purchased under |
| 171 | <u>Section 49-20-421.</u> |
| 172 | Section 7. Section 49-20-420 is enacted to read: |
| 173 | 49-20-420. Coverage of insulin. |
| 174 | (1) As used in this section, "lowest tier" means the lowest copayment tier of a health |
| 175 | benefit plan or the preventive drug tier of a high deductible health plan. |
| 176 | (2) Beginning January 1, 2021, the program shall: |
| 177 | (a) cap the total amount that an insured is required to pay for insulin at an amount not |
| 178 | to exceed \$30 per 30-day supply of insulin, regardless of the amount or type of insulin needed |
| 179 | to fill the insured's prescription; and |
| 180 | (b) apply the cap to an insured regardless of whether the insured has met the plan's |
| 181 | deductible. |
| 182 | Section 8. Section 49-20-421 is enacted to read: |

| 183 | 49-20-421. Purchasing of insulin. |
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| 184 | (1) As used in this section: |
| 185 | (a) "Diabetes" means: |
| 186 | (i) complete insulin deficiency or type 1 diabetes; |
| 187 | (ii) insulin resistant with partial insulin deficiency or type 2 diabetes; or |
| 188 | (iii) elevated blood glucose levels induced by pregnancy or gestational diabetes. |
| 189 | (b) "Discount program" means a process developed by the program that allows |
| 190 | participants to purchase insulin at a discounted rate. |
| 191 | (c) "Individual with diabetes" means an individual who has been diagnosed with |
| 192 | diabetes and who uses insulin to treat diabetes. |
| 193 | (d) "Insulin" means a prescription drug that contains insulin. |
| 194 | (e) "Participant" means a public employee who: |
| 195 | (i) uses insulin to treat diabetes; |
| 196 | (ii) does not receive health coverage under the program; and |
| 197 | (iii) has decided to participate in the discount program. |
| 198 | (f) "Public employee" means the same as that term is defined in Section 34-32-1.1. |
| 199 | (g) "Prescription drug" means the same as that term is defined in Section 58-17b-102. |
| 200 | (2) In accordance with Title 63G, Chapter 6A, Utah Procurement Code, the program |
| 201 | shall contract with insulin manufacturers to purchase insulin at a discounted price. |
| 202 | (3) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the |
| 203 | program shall make rules to develop a discount program to make the purchased insulin |
| 204 | available to participants at a discounted price. |
| 205 | (4) The discount program described in Subsection (3) shall: |
| 206 | (a) provide a participant with a card or electronic document that identifies the |
| 207 | participant as eligible for the discount; |
| 208 | (b) provide a participant with information about pharmacies that will honor the |
| 209 | discount; |
| 210 | (c) allow a participant to purchase insulin at the fully discounted, post-rebate price |
| 211 | described in Subsection (2); and |
| 212 | (d) provide a participant with instructions to pursue a refund of the purchase price from |
| 213 | the participant's health insurer. |

Section 9. Section **58-17b-102** is amended to read:

- 215 **58-17b-102. Definitions.**
- In addition to the definitions in Section 58-1-102, as used in this chapter:
- 217 (1) "Administering" means:

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- 218 (a) the direct application of a prescription drug or device, whether by injection, 219 inhalation, ingestion, or by any other means, to the body of a human patient or research subject 220 by another person; or
 - (b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.
- 225 (2) "Adulterated drug or device" means a drug or device considered adulterated under 226 21 U.S.C. Sec. 351 (2003).
 - (3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for the purpose of analysis.
 - (b) "Analytical laboratory" does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic use.
 - (4) "Animal euthanasia agency" means an agency performing euthanasia on animals by the use of prescription drugs.
 - (5) "Automated pharmacy systems" includes mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.
 - (6) "Beyond use date" means the date determined by a pharmacist and placed on a prescription label at the time of dispensing that indicates to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.
- 244 (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created

245 in Section 58-17b-201.

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- (8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically underserved area, used for the storage and dispensing of prescription drugs, which is dependent upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and approved by the division as the parent pharmacy.
- (9) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.
- (10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a retail pharmacy to compound or dispense a drug or dispense a device to the public under a prescription order.
 - (11) "Class B pharmacy":
 - (a) means a pharmacy located in Utah:
- (i) that is authorized to provide pharmaceutical care for patients in an institutional setting; and
- (ii) whose primary purpose is to provide a physical environment for patients to obtain health care services; and
 - (b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and
 - (ii) pharmaceutical administration and sterile product preparation facilities.
- (12) "Class C pharmacy" means a pharmacy that engages in the manufacture, production, wholesale, or distribution of drugs or devices in Utah.
 - (13) "Class D pharmacy" means a nonresident pharmacy.
 - (14) "Class E pharmacy" means all other pharmacies.
 - (15) (a) "Closed-door pharmacy" means a pharmacy that:
- (i) provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company; or
- (ii) engages exclusively in the practice of telepharmacy and does not serve walk-in retail customers.
 - (b) "Closed-door pharmacy" does not include a hospital pharmacy, a retailer of goods

to the general public, or the office of a practitioner.

(16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

- (17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.
- (18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:
- (i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;
- (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or
- (iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
 - (b) "Compounding" does not include:
- (i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;
- (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or
- (iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.
- (19) "Confidential information" has the same meaning as "protected health information" under the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.
 - (20) "Controlled substance" means the same as that term is defined in Section 58-37-2.
 - (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter

| 307 | 417, Sec. 3a(11) which is incorporated by reference. |
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| 308 | (22) "Dispense" means the interpretation, evaluation, and implementation of a |
| 309 | prescription drug order or device or nonprescription drug or device under a lawful order of a |
| 310 | practitioner in a suitable container appropriately labeled for subsequent administration to or use |
| 311 | by a patient, research subject, or an animal. |
| 312 | (23) "Dispensing medical practitioner" means an individual who is: |
| 313 | (a) currently licensed as: |
| 314 | (i) a physician and surgeon under Chapter 67, Utah Medical Practice Act; |
| 315 | (ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical |
| 316 | Practice Act; |
| 317 | (iii) a physician assistant under Chapter 70a, Utah Physician Assistant Act; |
| 318 | (iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or |
| 319 | (v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist |
| 320 | is acting within the scope of practice for an optometrist; and |
| 321 | (b) licensed by the division under the Pharmacy Practice Act to engage in the practice |
| 322 | of a dispensing medical practitioner. |
| 323 | (24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy |
| 324 | located within a licensed dispensing medical practitioner's place of practice. |
| 325 | (25) "Distribute" means to deliver a drug or device other than by administering or |
| 326 | dispensing. |
| 327 | (26) (a) "Drug" means: |
| 328 | (i) a substance recognized in the official United States Pharmacopoeia, official |
| 329 | Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any |
| 330 | supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or |
| 331 | prevention of disease in humans or animals; |
| 332 | (ii) a substance that is required by any applicable federal or state law or rule to be |
| 333 | dispensed by prescription only or is restricted to administration by practitioners only; |
| 334 | (iii) a substance other than food intended to affect the structure or any function of the |
| 335 | body of humans or other animals; and |
| 336 | (iv) substances intended for use as a component of any substance specified in |
| 337 | Subsections (26)(a)(i), (ii), (iii), and (iv). |

| 338 | (b) Drug does not include dietary supplements. |
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| 339 | (27) "Drug regimen review" includes the following activities: |
| 340 | (a) evaluation of the prescription drug order and patient record for: |
| 341 | (i) known allergies; |
| 342 | (ii) rational therapy-contraindications; |
| 343 | (iii) reasonable dose and route of administration; and |
| 344 | (iv) reasonable directions for use; |
| 345 | (b) evaluation of the prescription drug order and patient record for duplication of |
| 346 | therapy; |
| 347 | (c) evaluation of the prescription drug order and patient record for the following |
| 348 | interactions: |
| 349 | (i) drug-drug; |
| 350 | (ii) drug-food; |
| 351 | (iii) drug-disease; and |
| 352 | (iv) adverse drug reactions; and |
| 353 | (d) evaluation of the prescription drug order and patient record for proper utilization, |
| 354 | including over- or under-utilization, and optimum therapeutic outcomes. |
| 355 | (28) "Drug sample" means a prescription drug packaged in small quantities consistent |
| 356 | with limited dosage therapy of the particular drug, which is marked "sample", is not intended to |
| 357 | be sold, and is intended to be provided to practitioners for the immediate needs of patients for |
| 358 | trial purposes or to provide the drug to the patient until a prescription can be filled by the |
| 359 | patient. |
| 360 | (29) "Electronic signature" means a trusted, verifiable, and secure electronic sound, |
| 361 | symbol, or process attached to or logically associated with a record and executed or adopted by |
| 362 | a person with the intent to sign the record. |
| 363 | (30) "Electronic transmission" means transmission of information in electronic form or |
| 364 | the transmission of the exact visual image of a document by way of electronic equipment. |
| 365 | (31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to |
| 366 | inpatients of a general acute hospital or specialty hospital licensed by the Department of Health |
| 367 | under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act. |
| 368 | (32) "Insulin" means the same as that term is defined in Section 26-47-101 |

| 369 | $\left[\frac{32}{32}\right]$ (33) "Legend drug" has the same meaning as prescription drug. |
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| 370 | [(33)] (34) "Licensed pharmacy technician" means an individual licensed with the |
| 371 | division, that may, under the supervision of a pharmacist, perform the activities involved in the |
| 372 | technician practice of pharmacy. |
| 373 | [(34)] (35) "Manufacturer" means a person or business physically located in Utah |
| 374 | licensed to be engaged in the manufacturing of drugs or devices. |
| 375 | [(35)] <u>(36)</u> (a) "Manufacturing" means: |
| 376 | (i) the production, preparation, propagation, conversion, or processing of a drug or |
| 377 | device, either directly or indirectly, by extraction from substances of natural origin or |
| 378 | independently by means of chemical or biological synthesis, or by a combination of extraction |
| 379 | and chemical synthesis, and includes any packaging or repackaging of the substance or labeling |
| 380 | or relabeling of its container; and |
| 381 | (ii) the promotion and marketing of such drugs or devices. |
| 382 | (b) "Manufacturing" includes the preparation and promotion of commercially available |
| 383 | products from bulk compounds for resale by pharmacies, practitioners, or other persons. |
| 384 | (c) "Manufacturing" does not include the preparation or compounding of a drug by a |
| 385 | pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation, |
| 386 | compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical |
| 387 | analysis. |
| 388 | [(36)] (37) "Medical order" means a lawful order of a practitioner which may include a |
| 389 | prescription drug order. |
| 390 | [(37)] (38) "Medication profile" or "profile" means a record system maintained as to |
| 391 | drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to |
| 392 | analyze the profile to provide pharmaceutical care. |
| 393 | [(38)] (39) "Misbranded drug or device" means a drug or device considered |
| 394 | misbranded under 21 U.S.C. Sec. 352 (2003). |
| 395 | [(39)] (40) (a) "Nonprescription drug" means a drug which: |
| 396 | (i) may be sold without a prescription; and |
| 397 | (ii) is labeled for use by the consumer in accordance with federal law. |
| 398 | (b) "Nonprescription drug" includes homeopathic remedies. |

[(40)] (41) "Nonresident pharmacy" means a pharmacy located outside of Utah that

| 400 | sells to a person in Utah. |
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| 401 | [(41)] (42) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical |
| 402 | service. |
| 403 | [(42)] (43) "Out-of-state mail service pharmacy" means a pharmaceutical facility |
| 404 | located outside the state that is licensed and in good standing in another state, that: |
| 405 | (a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in |
| 406 | this state pursuant to a lawfully issued prescription; |
| 407 | (b) provides information to a patient in this state on drugs or devices which may |
| 408 | include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses; |
| 409 | or |
| 410 | (c) counsels pharmacy patients residing in this state concerning adverse and therapeutic |
| 411 | effects of drugs. |
| 412 | [(43)] (44) "Patient counseling" means the written and oral communication by the |
| 413 | pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure |
| 414 | proper use of drugs, devices, and dietary supplements. |
| 415 | [(44)] (45) "Pharmaceutical administration facility" means a facility, agency, or |
| 416 | institution in which: |
| 417 | (a) prescription drugs or devices are held, stored, or are otherwise under the control of |
| 418 | the facility or agency for administration to patients of that facility or agency; |
| 419 | (b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist |
| 420 | or pharmacy intern with whom the facility has established a prescription drug supervising |
| 421 | relationship under which the pharmacist or pharmacy intern provides counseling to the facility |
| 422 | or agency staff as required, and oversees drug control, accounting, and destruction; and |
| 423 | (c) prescription drugs are professionally administered in accordance with the order of a |
| 424 | practitioner by an employee or agent of the facility or agency. |
| 425 | [(45)] (46) (a) "Pharmaceutical care" means carrying out the following in collaboration |
| 426 | with a prescribing practitioner, and in accordance with division rule: |
| 427 | (i) designing, implementing, and monitoring a therapeutic drug plan intended to |
| 428 | achieve favorable outcomes related to a specific patient for the purpose of curing or preventing |

(ii) eliminating or reducing a patient's symptoms; or

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the patient's disease;

manufacturer; and

| 431 | (iii) arresting or slowing a disease process. |
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| 432 | (b) "Pharmaceutical care" does not include prescribing of drugs without consent of a |
| 433 | prescribing practitioner. |
| 434 | [(46)] (47) "Pharmaceutical facility" means a business engaged in the dispensing, |
| 435 | delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within |
| 436 | or into this state. |
| 437 | [(47)] (48) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical |
| 438 | facility engaged in the business of wholesale vending or selling of a prescription drug or device |
| 439 | to other than a consumer or user of the prescription drug or device that the pharmaceutical |
| 440 | facility has not produced, manufactured, compounded, or dispensed. |
| 441 | (b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical |
| 442 | facility carrying out the following business activities: |
| 443 | (i) intracompany sales; |
| 444 | (ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, |
| 445 | purchase, or trade a prescription drug or device, if the activity is carried out between one or |
| 446 | more of the following entities under common ownership or common administrative control, as |
| 447 | defined by division rule: |
| 448 | (A) hospitals; |
| 449 | (B) pharmacies; |
| 450 | (C) chain pharmacy warehouses, as defined by division rule; or |
| 451 | (D) other health care entities, as defined by division rule; |
| 452 | (iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, |
| 453 | purchase, or trade a prescription drug or device, for emergency medical reasons, including |
| 454 | supplying another pharmaceutical facility with a limited quantity of a drug, if: |
| 455 | (A) the facility is unable to obtain the drug through a normal distribution channel in |
| 456 | sufficient time to eliminate the risk of harm to a patient that would result from a delay in |
| 457 | obtaining the drug; and |
| 458 | (B) the quantity of the drug does not exceed an amount reasonably required for |
| 459 | immediate dispensing to eliminate the risk of harm; |

(iv) the distribution of a prescription drug or device as a sample by representatives of a

| 462 | (v) the distribution of prescription drugs, if: |
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| 463 | (A) the facility's total distribution-related sales of prescription drugs does not exceed |
| 464 | 5% of the facility's total prescription drug sales; and |
| 465 | (B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11. |
| 466 | [(48)] (49) "Pharmacist" means an individual licensed by this state to engage in the |
| 467 | practice of pharmacy. |
| 468 | [(49)] (50) "Pharmacist-in-charge" means a pharmacist currently licensed in good |
| 469 | standing who accepts responsibility for the operation of a pharmacy in conformance with all |
| 470 | laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is |
| 471 | personally in full and actual charge of the pharmacy and all personnel. |
| 472 | [(50)] (51) "Pharmacist preceptor" means a licensed pharmacist in good standing with |
| 473 | one or more years of licensed experience. The preceptor serves as a teacher, example of |
| 474 | professional conduct, and supervisor of interns in the professional practice of pharmacy. |
| 475 | [(51)] (52) "Pharmacy" means any place where: |
| 476 | (a) drugs are dispensed; |
| 477 | (b) pharmaceutical care is provided; |
| 478 | (c) drugs are processed or handled for eventual use by a patient; or |
| 479 | (d) drugs are used for the purpose of analysis or research. |
| 480 | [(52)] (53) "Pharmacy benefits manager or coordinator" means a person or entity that |
| 481 | provides a pharmacy benefits management service as defined in Section 49-20-502 on behalf of |
| 482 | a self-insured employer, insurance company, health maintenance organization, or other plan |
| 483 | sponsor, as defined by rule. |
| 484 | [(53)] (54) "Pharmacy intern" means an individual licensed by this state to engage in |
| 485 | practice as a pharmacy intern. |
| 486 | [(54)] (55) "Pharmacy technician training program" means an approved technician |
| 487 | training program providing education for pharmacy technicians. |
| 488 | [(55)] (26) (a) "Practice as a dispensing medical practitioner" means the practice of |
| 489 | pharmacy, specifically relating to the dispensing of a prescription drug in accordance with Part |
| 490 | 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, and |
| 491 | division rule adopted after consultation with the Board of pharmacy and the governing boards |
| 492 | of the practitioners described in Subsection (23)(a). |

| 493 | (b) "Practice as a dispensing medical practitioner" does not include: |
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| 494 | (i) using a vending type of dispenser as defined by the division by administrative rule; |
| 495 | or |
| 496 | (ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as |
| 497 | defined in Section 58-37-2. |
| 498 | [(56)] (57) "Practice as a licensed pharmacy technician" means engaging in practice as |
| 499 | a pharmacy technician under the general supervision of a licensed pharmacist and in |
| 500 | accordance with a scope of practice defined by division rule made in collaboration with the |
| 501 | board. |
| 502 | [(57)] (58) "Practice of pharmacy" includes the following: |
| 503 | (a) providing pharmaceutical care; |
| 504 | (b) collaborative pharmacy practice in accordance with a collaborative pharmacy |
| 505 | practice agreement; |
| 506 | (c) compounding, packaging, labeling, dispensing, administering, and the coincident |
| 507 | distribution of prescription drugs or devices, provided that the administration of a prescription |
| 508 | drug or device is: |
| 509 | (i) pursuant to a lawful order of a practitioner when one is required by law; and |
| 510 | (ii) in accordance with written guidelines or protocols: |
| 511 | (A) established by the licensed facility in which the prescription drug or device is to be |
| 512 | administered on an inpatient basis; or |
| 513 | (B) approved by the division, in collaboration with the board and the Physicians |
| 514 | Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be |
| 515 | administered on an outpatient basis solely by a licensed pharmacist; |
| 516 | (d) participating in drug utilization review; |
| 517 | (e) ensuring proper and safe storage of drugs and devices; |
| 518 | (f) maintaining records of drugs and devices in accordance with state and federal law |
| 519 | and the standards and ethics of the profession; |
| 520 | (g) providing information on drugs or devices, which may include advice relating to |
| 521 | therapeutic values, potential hazards, and uses; |
| 522 | (h) providing drug product equivalents; |
| 523 | (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy |

| 324 | technicians, |
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| 525 | (j) providing patient counseling, including adverse and therapeutic effects of drugs; |
| 526 | (k) providing emergency refills as defined by rule; |
| 527 | (l) telepharmacy; |
| 528 | (m) formulary management intervention; [and] |
| 529 | (n) prescribing and dispensing a self-administered hormonal contraceptive in |
| 530 | accordance with Title 26, Chapter 64, Family Planning Access Act[-]; and |
| 531 | (o) prescribing and dispensing insulin in accordance with Title 26, Chapter 67, Insulin |
| 532 | Access Act. |
| 533 | [(58)] (59) "Practice of telepharmacy" means the practice of pharmacy through the use |
| 534 | of telecommunications and information technologies. |
| 535 | [(59)] (60) "Practice of telepharmacy across state lines" means the practice of |
| 536 | pharmacy through the use of telecommunications and information technologies that occurs |
| 537 | when the patient is physically located within one jurisdiction and the pharmacist is located in |
| 538 | another jurisdiction. |
| 539 | [(60)] (61) "Practitioner" means an individual currently licensed, registered, or |
| 540 | otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the |
| 541 | course of professional practice. |
| 542 | [(61)] <u>(62)</u> "Prescribe" means to issue a prescription: |
| 543 | (a) orally or in writing; or |
| 544 | (b) by telephone, facsimile transmission, computer, or other electronic means of |
| 545 | communication as defined by division rule. |
| 546 | [(62)] (63) "Prescription" means an order issued: |
| 547 | (a) by a licensed practitioner in the course of that practitioner's professional practice or |
| 548 | by collaborative pharmacy practice agreement; and |
| 549 | (b) for a controlled substance or other prescription drug or device for use by a patient |
| 550 | or an animal. |
| 551 | [(63)] (64) "Prescription device" means an instrument, apparatus, implement, machine, |
| 552 | contrivance, implant, in vitro reagent, or other similar or related article, and any component |
| 553 | part or accessory, which is required under federal or state law to be prescribed by a practitioner |
| 554 | and dispensed by or through a person or entity licensed under this chapter or exempt from |

| 555 | licensure under this chapter. |
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| 556 | [(64)] (65) "Prescription drug" means a drug that is required by federal or state law or |
| 557 | rule to be dispensed only by prescription or is restricted to administration only by practitioners. |
| 558 | [(65)] <u>(66)</u> "Repackage": |
| 559 | (a) means changing the container, wrapper, or labeling to further the distribution of a |
| 560 | prescription drug; and |
| 561 | (b) does not include: |
| 562 | (i) Subsection [(65)] (66)(a) when completed by the pharmacist responsible for |
| 563 | dispensing the product to a patient; or |
| 564 | (ii) changing or altering a label as necessary for a dispensing practitioner under Part 8, |
| 565 | Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for |
| 566 | dispensing a product to a patient. |
| 567 | [(66)] (67) "Research using pharmaceuticals" means research: |
| 568 | (a) conducted in a research facility, as defined by division rule, that is associated with a |
| 569 | university or college in the state accredited by the Northwest Commission on Colleges and |
| 570 | Universities; |
| 571 | (b) requiring the use of a controlled substance, prescription drug, or prescription |
| 572 | device; |
| 573 | (c) that uses the controlled substance, prescription drug, or prescription device in |
| 574 | accordance with standard research protocols and techniques, including, if required, those |
| 575 | approved by an institutional review committee; and |
| 576 | (d) that includes any documentation required for the conduct of the research and the |
| 577 | handling of the controlled substance, prescription drug, or prescription device. |
| 578 | [(67)] (68) "Retail pharmacy" means a pharmaceutical facility dispensing prescription |
| 579 | drugs and devices to the general public. |
| 580 | [(68)] (69) (a) "Self-administered hormonal contraceptive" means a self-administered |
| 581 | hormonal contraceptive that is approved by the United States Food and Drug Administration to |
| 582 | prevent pregnancy. |
| 583 | (b) "Self-administered hormonal contraceptive" includes an oral hormonal |
| 584 | contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch. |

(c) "Self-administered hormonal contraceptive" does not include any drug intended to

586 induce an abortion, as that term is defined in Section 76-7-301. [(69)] (70) "Self-audit" means an internal evaluation of a pharmacy to determine 587 588 compliance with this chapter. 589 [(70)] (71) "Supervising pharmacist" means a pharmacist who is overseeing the 590 operation of the pharmacy during a given day or shift. 591 [(71)] (72) "Supportive personnel" means unlicensed individuals who: (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed 592 593 pharmacy technician in nonjudgmental duties not included in the definition of the practice of 594 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as 595 those duties may be further defined by division rule adopted in collaboration with the board; 596 and 597 (b) are supervised by a pharmacist in accordance with rules adopted by the division in 598 collaboration with the board. 599 $\left[\frac{72}{12}\right]$ (73) "Unlawful conduct" means the same as that term is defined in Sections 600 58-1-501 and 58-17b-501. 601 [(73)] (74) "Unprofessional conduct" means the same as that term is defined in 602 Sections 58-1-501 and 58-17b-502 and may be further defined by rule. [(74)] (75) "Veterinary pharmaceutical facility" means a pharmaceutical facility that 603 604 dispenses drugs intended for use by animals or for sale to veterinarians for the administration 605 for animals. 606 Section 10. Section **58-17b-501** is amended to read: 607 58-17b-501. Unlawful conduct. 608 "Unlawful conduct" includes: 609 (1) knowingly preventing or refusing to permit an authorized agent of the division to 610 conduct an inspection pursuant to Section 58-17b-103; 611 (2) failing to deliver the license, permit, or certificate to the division upon demand, if it 612 has been revoked, suspended, or refused; 613 (3) (a) using the title "pharmacist," "druggist," "pharmacy intern," "pharmacy 614 technician," or a term having similar meaning, except by a person licensed as a pharmacist, pharmacy intern, or pharmacy technician; or 615 616 (b) conducting or transacting business under a name that contains, as part of that name,

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| the words "drugstore," "pharmacy," "drugs," "medicine store," "medicines," "drug shop," |
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| "apothecary," "prescriptions," or a term having a similar meaning, or in any manner |
| advertising, otherwise describing, or referring to the place of the conducted business or |
| profession, unless the place is a pharmacy issued a license by the division, except an |
| establishment selling nonprescription drugs and supplies may display signs bearing the words |
| "packaged drugs," "drug sundries," or "nonprescription drugs," and is not considered to be a |
| pharmacy or drugstore by reason of the display; |

- (4) buying, selling, causing to be sold, or offering for sale, a drug or device that bears, or the package bears or originally did bear, the inscription "sample," "not for resale," "for investigational or experimental use only," or other similar words, except when a cost is incurred in the bona fide acquisition of an investigational or experimental drug;
- (5) using to a person's own advantages or revealing to anyone other than the division, board, and its authorized representatives, or to the courts, when relevant to a judicial or administrative proceeding under this chapter, information acquired under authority of this chapter or concerning a method of process that is a trade secret;
- (6) procuring or attempting to procure a drug or to have someone else procure or attempt to procure a drug:
 - (a) by fraud, deceit, misrepresentation, or subterfuge;
 - (b) by forgery or alteration of a prescription or a written order;
 - (c) by concealment of a material fact;
 - (d) by use of a false statement in a prescription, chart, order, or report; or
- 638 (e) by theft;
 - (7) filling, refilling, or advertising the filling or refilling of prescriptions for a consumer or patient residing in this state if the person is not licensed:
 - (a) under this chapter; or
 - (b) in the state from which he is dispensing;
 - (8) requiring an employed pharmacist, pharmacy intern, pharmacy technician, or authorized supportive personnel to engage in conduct in violation of this chapter;
 - (9) being in possession of a prescription drug for an unlawful purpose;
- 646 (10) dispensing a prescription drug to a person who does not have a prescription from a 647 practitioner, except as permitted under:

| 648 | (a) Title 26, Chapter 55, Opiate Overdose Response Act; [or] |
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| 649 | (b) Title 26, Chapter 64, Family Planning Access Act; or |
| 650 | (c) Title 26, Chapter 67, Insulin Access Act; |
| 651 | (11) dispensing a prescription drug to a person who the person dispensing the drug |
| 652 | knows or should know is attempting to obtain drugs by fraud or misrepresentation; |
| 653 | (12) selling, dispensing, distributing, or otherwise trafficking in prescription drugs |
| 654 | when not licensed to do so or when not exempted from licensure; and |
| 655 | (13) a person using a prescription drug or controlled substance that was not lawfully |
| 656 | prescribed for the person by a practitioner. |
| 657 | Section 11. Section 58-17b-608.2 is enacted to read: |
| 658 | 58-17b-608.2. Insulin prescriptions. |
| 659 | (1) If a prescription for insulin includes authorization for one or more refills, a |
| 660 | pharmacist or a pharmacy intern may dispense one or more of the refills in an amount up to a |
| 661 | supply for 90 days based on the prescriber's instructions if: |
| 662 | (a) the patient has previously had the prescription; and |
| 663 | (b) filling the prescription is consistent with the training and experience of the |
| 664 | pharmacist or pharmacy intern. |
| 665 | (2) If a prescription for insulin includes authorization for one or more refills, a |
| 666 | pharamcist or a pharmacy intern may dispense one or more of the refills in an amount to |
| 667 | exceed 90 days if: |
| 668 | (a) the patient has previously had the prescription; |
| 669 | (b) filling the prescription is consistent with the training and experieince of the |
| 670 | pharmacist or pharmacy intern; and |
| 671 | (c) circumstances justify filling the prescription for longer. |
| 672 | (3) A practitioner is authorized to issue a prescription for insulin that is refillable for up |
| 673 | to three years. |
| 674 | Section 12. Section 58-17b-609 is amended to read: |
| 675 | 58-17b-609. Limitation on prescriptions and refills Controlled Substances Act |
| 676 | not affected Legend drugs. |
| 677 | (1) Except as provided in [Section] Sections 58-16a-102 and 58-17b-608.2, a |
| 678 | prescription for any prescription drug or device may not be dispensed after one year from the |

01-28-20 10:44 AM 679 date it was initiated except as otherwise provided in Chapter 37, Utah Controlled Substances 680 Act. 681 (2) A prescription authorized to be refilled may not be refilled after one year from the 682 original issue date. 683 (3) A practitioner may not be prohibited from issuing a new prescription for the same 684 drug orally, in writing, or by electronic transmission. 685 (4) Nothing in this chapter affects Chapter 37, Utah Controlled Substances Act. (5) A prescription for a legend drug written by a licensed prescribing practitioner in 686 687 another state may be filled or refilled by a pharmacist or pharmacy intern in this state if the 688 pharmacist or pharmacy intern verifies that the prescription is valid. 689 Section 13. Section **58-17b-612** is amended to read: 690 58-17b-612. Supervision -- Pharmacist-in-charge. 691 (1) (a) Any pharmacy, except a wholesaler, distributor, out-of-state mail service 692 pharmacy, or class E pharmacy, shall be under the general supervision of at least one 693 pharmacist licensed to practice in Utah. One pharmacist licensed in Utah shall be designated 694 695

- as the pharmacist-in-charge, whose responsibility it is to oversee the operation of the pharmacy.
- (b) Notwithstanding Subsection $58-17b-102[\frac{(70)}{(71)}]$ (71), a supervising pharmacist does not have to be in the pharmacy or care facility but shall be available via a telepharmacy system for immediate contact with the supervised pharmacy technician or pharmacy intern if:

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- (i) the pharmacy is located in an area of need as defined by the division, in consultation with the board, by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act;
 - (ii) the supervising pharmacist described in Subsection (1)(a) is not available;
- (iii) the telepharmacy system maintains records and files quarterly reports as required by division rule to assure that patient safety is not compromised; and
 - (iv) the arrangement is approved by the division in collaboration with the board.
- (c) Subsection (1)(b) applies to a pharmacy that is located in a hospital only if the hospital is controlled by a local board that owns no more than two hospitals; and
- (d) A supervising pharmacist may not supervise more than two pharmacies simultaneously under Subsection (1)(b).
 - (2) Each out-of-state mail service pharmacy shall designate and identify to the division

| 710 | a pharmacist holding a current license in good standing issued by the state in which the |
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| 711 | pharmacy is located and who serves as the pharmacist-in-charge for all purposes under this |
| 712 | chapter. |
| 713 | Section 14. Section 58-17b-625 is amended to read: |
| 714 | 58-17b-625. Administration of a long-acting injectable drug therapy. |
| 715 | (1) A pharmacist may, in accordance with this section, administer a drug described in |
| 716 | Subsection (2). |
| 717 | (2) Notwithstanding the provisions of Subsection 58-17b-102[(57)](58)(c)(ii)(B), the |
| 718 | division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative |
| 719 | Rulemaking Act, establishing training for a pharmacist to administer the following long-acting |
| 720 | injectables intramuscularly: |
| 721 | (a) aripiprazole; |
| 722 | (b) aripiprazole lauroxil; |
| 723 | (c) paliperidone; |
| 724 | (d) risperidone; |
| 725 | (e) olanzapine; |
| 726 | (f) naltrexone; |
| 727 | (g) naloxone; and |
| 728 | (h) drugs approved and regulated by the United States Food and Drug Administration |
| 729 | for the treatment of the Human Immunodeficiency Virus. |
| 730 | (3) A pharmacist may not administer a drug listed under Subsection (2) unless the |
| 731 | pharmacist: |
| 732 | (a) completes the training described in Subsection (2); |
| 733 | (b) administers the drug at a clinic or community pharmacy, as those terms are defined |
| 734 | by the division, by administrative rule made in accordance with Title 63G, Chapter 3, Utah |
| 735 | Administrative Rulemaking Act; and |
| 736 | (c) is directed by the physician, as that term is defined in Section 58-67-102 or Section |
| 737 | 58-68-102, who issues the prescription to administer the drug. |
| 738 | Section 15. Section 58-31b-102 is amended to read: |
| 739 | 58-31h-102 Definitions |

In addition to the definitions in Section 58-1-102, as used in this chapter:

- (1) "Administrative penalty" means a monetary fine or citation imposed by the division for acts or omissions determined to constitute unprofessional or unlawful conduct in accordance with a fine schedule established by rule and as a result of an adjudicative proceeding conducted in accordance with Title 63G, Chapter 4, Administrative Procedures Act.
- (2) "Applicant" means a person who applies for licensure or certification under this chapter by submitting a completed application for licensure or certification and the required fees to the department.
- (3) "Approved education program" means a nursing education program that is accredited by an accrediting body for nursing education that is approved by the United States Department of Education.
 - (4) "Board" means the Board of Nursing created in Section 58-31b-201.
- (5) "Consultation and referral plan" means a written plan jointly developed by an advanced practice registered nurse and, except as provided in Subsection 58-31b-803(4), a consulting physician that permits the advanced practice registered nurse to prescribe Schedule II controlled substances in consultation with the consulting physician.
- (6) "Consulting physician" means a physician and surgeon or osteopathic physician and surgeon licensed in accordance with this title who has agreed to consult with an advanced practice registered nurse with a controlled substance license, a DEA registration number, and who will be prescribing Schedule II controlled substances.
- (7) "Diagnosis" means the identification of and discrimination between physical and psychosocial signs and symptoms essential to the effective execution and management of health care.
- (8) "Examinee" means a person who applies to take or does take any examination required under this chapter for licensure.
 - (9) "Insulin" means the same as that term is defined in Section 26-47-101.
 - [(9)] (10) "Licensee" means a person who is licensed or certified under this chapter.
- [(10)] (11) "Long-term care facility" means any of the following facilities licensed by the Department of Health pursuant to Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act:
- (a) a nursing care facility;
- (b) a small health care facility;

| 772 | (c) an intermediate care facility for people with an intellectual disability; |
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| 773 | (d) an assisted living facility Type I or II; or |
| 774 | (e) a designated swing bed unit in a general hospital. |
| 775 | [(11)] (12) "Medication aide certified" means a certified nurse aide who: |
| 776 | (a) has a minimum of 2,000 hours experience working as a certified nurse aide; |
| 777 | (b) has received a minimum of 60 hours of classroom and 40 hours of practical training |
| 778 | that is approved by the division in collaboration with the board, in administering routine |
| 779 | medications to patients or residents of long-term care facilities; and |
| 780 | (c) is certified by the division as a medication aide certified. |
| 781 | $\left[\frac{(12)}{(13)}\right]$ "Pain clinic" means the same as that term is defined in Section 58-1-102. |
| 782 | [(13)] (14) (a) "Practice as a medication aide certified" means the limited practice of |
| 783 | nursing under the supervision, as defined by the division by administrative rule, of a licensed |
| 784 | nurse, involving routine patient care that requires minimal or limited specialized or general |
| 785 | knowledge, judgment, and skill, to an individual who: |
| 786 | (i) is ill, injured, infirm, has a physical, mental, developmental, or intellectual |
| 787 | disability; and |
| 788 | (ii) is in a regulated long-term care facility. |
| 789 | (b) "Practice as a medication aide certified": |
| 790 | (i) includes: |
| 791 | (A) providing direct personal assistance or care; and |
| 792 | (B) administering routine medications to patients in accordance with a formulary and |
| 793 | protocols to be defined by the division by rule; and |
| 794 | (ii) does not include assisting a resident of an assisted living facility, a long term care |
| 795 | facility, or an intermediate care facility for people with an intellectual disability to self |
| 796 | administer a medication, as regulated by the Department of Health by administrative rule. |
| 797 | [(14)] (15) "Practice of advanced practice registered nursing" means the practice of |
| 798 | nursing within the generally recognized scope and standards of advanced practice registered |
| 799 | nursing as defined by rule and consistent with professionally recognized preparation and |
| 800 | education standards of an advanced practice registered nurse by a person licensed under this |
| 801 | chapter as an advanced practice registered nurse. Advanced practice registered nursing |
| 802 | includes: |

| 803 | (a) maintenance and promotion of health and prevention of disease; |
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| 804 | (b) diagnosis, treatment, correction, consultation, and referral for common health |
| 805 | problems; |
| 806 | (c) prescription or administration of prescription drugs or devices including: |
| 807 | (i) local anesthesia; |
| 808 | (ii) Schedule III-V controlled substances; and |
| 809 | (iii) Subject to Section 58-31b-803, Schedule II controlled substances; or |
| 810 | (d) the provision of preoperative, intraoperative, and postoperative anesthesia care and |
| 811 | related services upon the request of a licensed health care professional by an advanced practice |
| 812 | registered nurse specializing as a certified registered nurse anesthetist, including: |
| 813 | (i) preanesthesia preparation and evaluation including: |
| 814 | (A) performing a preanesthetic assessment of the patient; |
| 815 | (B) ordering and evaluating appropriate lab and other studies to determine the health of |
| 816 | the patient; and |
| 817 | (C) selecting, ordering, or administering appropriate medications; |
| 818 | (ii) anesthesia induction, maintenance, and emergence, including: |
| 819 | (A) selecting and initiating the planned anesthetic technique; |
| 820 | (B) selecting and administering anesthetics and adjunct drugs and fluids; and |
| 821 | (C) administering general, regional, and local anesthesia; |
| 822 | (iii) postanesthesia follow-up care, including: |
| 823 | (A) evaluating the patient's response to anesthesia and implementing corrective |
| 824 | actions; and |
| 825 | (B) selecting, ordering, or administering the medications and studies listed in |
| 826 | Subsection [(14)] (15)(d); [and] |
| 827 | (iv) other related services within the scope of practice of a certified registered nurse |
| 828 | anesthetist, including: |
| 829 | (A) emergency airway management; |
| 830 | (B) advanced cardiac life support; and |
| 831 | (C) the establishment of peripheral, central, and arterial invasive lines; and |
| 832 | (v) for purposes of Subsection $[\frac{(14)}{(15)}]$ (15) (d), "upon the request of a licensed health |
| 833 | care professional": |

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indirectly; and

(A) means a health care professional practicing within the scope of the health care professional's license, requests anesthesia services for a specific patient; and (B) does not require an advanced practice registered nurse specializing as a certified registered nurse anesthetist to enter into a consultation and referral plan or obtain additional authority to select, administer, or provide preoperative, intraoperative, or postoperative anesthesia care and services. [(15)] (16) "Practice of nursing" means assisting individuals or groups to maintain or attain optimal health, implementing a strategy of care to accomplish defined goals and evaluating responses to care and treatment. The practice of nursing requires substantial specialized or general knowledge, judgment, and skill based upon principles of the biological, physical, behavioral, and social sciences, and includes: (a) initiating and maintaining comfort measures; (b) promoting and supporting human functions and responses: (c) establishing an environment conducive to well-being; (d) providing health counseling and teaching; (e) collaborating with health care professionals on aspects of the health care regimen; (f) performing delegated procedures only within the education, knowledge, judgment, and skill of the licensee: and (g) delegating nurse interventions that may be performed by others and are not in conflict with this chapter. [(16)] (17) "Practice of practical nursing" means the performance of nursing acts in the generally recognized scope of practice of licensed practical nurses as defined by rule and as provided in this Subsection [(16)] (17) by a person licensed under this chapter as a licensed practical nurse and under the direction of a registered nurse, licensed physician, or other specified health care professional as defined by rule. Practical nursing acts include: (a) contributing to the assessment of the health status of individuals and groups; (b) participating in the development and modification of the strategy of care; (c) implementing appropriate aspects of the strategy of care;

(e) participating in the evaluation of responses to interventions.

(d) maintaining safe and effective nursing care rendered to a patient directly or

| 865 | [(17)] (18) "Practice of registered nursing" means performing acts of nursing as |
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| 866 | provided in this Subsection $[(17)]$ (18) by a person licensed under this chapter as a registered |
| 867 | nurse within the generally recognized scope of practice of registered nurses as defined by rule[- |
| 868 | Registered nursing acts include], including: |
| 869 | (a) assessing the health status of individuals and groups; |
| 870 | (b) identifying health care needs; |
| 871 | (c) establishing goals to meet identified health care needs; |
| 872 | (d) planning a strategy of care; |
| 873 | (e) prescribing nursing interventions to implement the strategy of care; |
| 874 | (f) implementing the strategy of care; |
| 875 | (g) maintaining safe and effective nursing care that is rendered to a patient directly or |
| 876 | indirectly; |
| 877 | (h) evaluating responses to interventions; |
| 878 | (i) teaching the theory and practice of nursing; [and] |
| 879 | (j) managing and supervising the practice of nursing[-]; and |
| 880 | (k) prescribing insulin in accordance with Title 26, Chapter 67, Insulin Access Act. |
| 881 | (19) "Prescribe" means the same as that term is defined in Section 58-17b-102. |
| 882 | [(18)] <u>(20)</u> "Routine medications": |
| 883 | (a) means established medications administered to a medically stable individual as |
| 884 | determined by a licensed health care practitioner or in consultation with a licensed medical |
| 885 | practitioner; and |
| 886 | (b) is limited to medications that are administered by the following routes: |
| 887 | (i) oral; |
| 888 | (ii) sublingual; |
| 889 | (iii) buccal; |
| 890 | (iv) eye; |
| 891 | (v) ear; |
| 892 | (vi) nasal; |
| 893 | (vii) rectal; |
| 894 | (viii) vaginal; |
| 895 | (ix) skin ointments, topical including patches and transdermal: |

| 896 | (x) premeasured medication delivered by aerosol/nebulizer; and |
|-----|--|
| 897 | (xi) medications delivered by metered hand-held inhalers. |
| 898 | [(19)] (21) "Unlawful conduct" means the same as that term is defined in Sections |
| 899 | 58-1-501 and 58-31b-501. |
| 900 | [(20)] (22) "Unlicensed assistive personnel" means any unlicensed person, regardless |
| 901 | of title, to whom tasks are delegated by a licensed nurse as permitted by rule and in accordance |
| 902 | with the standards of the profession. |
| 903 | [(21)] (23) "Unprofessional conduct" means the same as that term is defined in |
| 904 | Sections 58-1-501 and 58-31b-502 and as may be further defined by rule. |
| 905 | Section 16. Section 58-31b-803 is amended to read: |
| 906 | 58-31b-803. Limitations on prescriptive authority for advanced practice |
| 907 | registered nurses. |
| 908 | (1) This section does not apply to an advanced practice registered nurse specializing as |
| 909 | a certified registered nurse anesthetist [under Subsection 58-31b-102(14)(d)] as defined in |
| 910 | Section 58-31b-102. |
| 911 | (2) Except as provided in Subsections (3) and 58-31b-502(1)(r), an advanced practice |
| 912 | registered nurse may prescribe or administer a Schedule II controlled substance without a |
| 913 | consultation and referral plan. |
| 914 | (3) An advanced practice registered nurse described in Subsection (4) may not |
| 915 | prescribe or administer a Schedule II controlled substance unless the advanced practice |
| 916 | registered nurse prescribes or administers Schedule II controlled substances in accordance with |
| 917 | a consultation and referral plan. |
| 918 | (4) Subsection (3) applies to an advanced practice registered nurse who: |
| 919 | (a) (i) is engaged in independent solo practice; and |
| 920 | (ii) (A) has been licensed as an advanced practice registered nurse for less than one |
| 921 | year; or |
| 922 | (B) has less than 2,000 hours of experience practicing as a licensed advanced practice |
| 923 | registered nurse; or |
| 924 | (b) owns or operates a pain clinic. |
| 925 | (5) Notwithstanding Subsection 58-31b-102(5), an advanced practice registered nurse |
| 926 | with at least three years of experience as a licensed advanced practice registered nurse may |

foster child:

| 927 | supervise a consultation and referral plan for an advanced practice registered nurse described in |
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| 928 | Subsection (4)(a). |
| 929 | Section 17. Section 62A-4a-213 is amended to read: |
| 930 | 62A-4a-213. Psychotropic medication oversight pilot program. |
| 931 | (1) As used in this section, "psychotropic medication" means medication prescribed to |
| 932 | affect or alter thought processes, mood, or behavior, including antipsychotic, antidepressant, |
| 933 | anxiolytic, or behavior medication. |
| 934 | (2) The division shall, through contract with the Department of Health, establish and |
| 935 | operate a psychotropic medication oversight pilot program for children in foster care to ensure |
| 936 | that foster children are being prescribed psychotropic medication consistent with their needs. |
| 937 | (3) The division shall establish an oversight team to manage the psychotropic |
| 938 | medication oversight program, composed of at least the following individuals: |
| 939 | (a) an "advanced practice registered nurse," as defined in [Subsection] Section |
| 940 | 58-31b-102[(14)], employed by the Department of Health; and |
| 941 | (b) a child psychiatrist. |
| 942 | (4) The oversight team shall monitor foster children: |
| 943 | (a) six years old or younger who are being prescribed one or more psychotropic |
| 944 | medications; and |
| 945 | (b) seven years old or older who are being prescribed two or more psychotropic |
| 946 | medications. |
| 947 | (5) The oversight team shall, upon request, be given information or records related to |
| 948 | the foster child's health care history, including psychotropic medication history and mental and |
| 949 | behavioral health history, from: |
| 950 | (a) the foster child's current or past caseworker; |
| 951 | (b) the foster child; or |
| 952 | (c) the foster child's: |
| 953 | (i) current or past health care provider; |
| 954 | (ii) natural parents; or |
| 955 | (iii) foster parents. |
| 956 | (6) The oversight team may review and monitor the following information about a |

| 958 | (a) the foster child's history; |
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| 959 | (b) the foster child's health care, including psychotropic medication history and mental |
| 960 | or behavioral health history; |
| 961 | (c) whether there are less invasive treatment options available to meet the foster child's |
| 962 | needs; |
| 963 | (d) the dosage or dosage range and appropriateness of the foster child's psychotropic |
| 964 | medication; |
| 965 | (e) the short-term or long-term risks associated with the use of the foster child's |
| 966 | psychotropic medication; or |
| 967 | (f) the reported benefits of the foster child's psychotropic medication. |
| 968 | (7) (a) The oversight team may make recommendations to the foster child's health care |
| 969 | providers concerning the foster child's psychotropic medication or the foster child's mental or |
| 970 | behavioral health. |
| 971 | (b) The oversight team shall provide the recommendations made in Subsection (7)(a) |
| 972 | to the foster child's parent or guardian after discussing the recommendations with the foster |
| 973 | child's current health care providers. |
| 974 | (8) The division may adopt administrative rules in accordance with Title 63G, Chapter |
| 975 | 3, Utah Administrative Rulemaking Act, necessary to administer this section. |
| 976 | (9) The division shall report to the Child Welfare Legislative Oversight Panel |
| 977 | regarding the psychotropic medication oversight pilot program by October 1 of each even |
| 978 | numbered year. |
| 979 | Section 18. Effective date. |

980 This bill takes effect on May 12, 2020, except that the amendments to Sections 981 31a-22-626 and 49-20-420 take effect on January 1, 2021.