Federal Guidance on Emergency Drug Kits Containing Controlled Substances

http://www.deadiversion.usdoj.gov/faq/general.htm
(Frequently Asked Questions from DEA Diversion website)

(Original publication of in the Federal Register / Vol. 45, No 70 / Wednesday, April 9, 1980)

Question: Can an LTCF store controlled substances in an emergency kit without being registered with DEA?

Answer: DEA published the following Statement of Policy in the April 9, 1980 Federal Register regarding the placement of controlled substances in an emergency kit located in an LTCF.

STATEMENT OF POLICY

The placement of emergency kits containing controlled substances in non-federally registered Long Term Care Facilities (LTCF) shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate:

A. **The source from which an LTCF may obtain controlled substances for emergency kits.** The source of supply must be a DEA registered hospital/clinic, pharmacy, or practitioner.

B. **Security safeguards for each emergency kit stored in the LTCF** which include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

C. **Responsibility for proper control and accountability of such emergency kits within the LTCF** to include the requirement that the LTCF and the providing DEA registered hospital/clinic, pharmacy, or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of these controlled substances plus the requirement to take periodic physical inventories.

D. **The emergency medical conditions under which the controlled substances may be administered to patients** in the LTCF to include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21.

E. **Prohibited activities which can result in the state revocation, denial, or suspension** of the privilege of having or placing emergency kits, containing controlled substances, in an LTCF.

IMPORTANT POINTS

- 21 CFR 1306.11: pertains to the requirements of a CII prescription and only being able to dispense a prescription pursuant to a prescription.

- 21 CFR 1306.21: pertains to the requirements of a CIII-V prescription and only being able to dispense a prescription pursuant to a prescription.
Emergency Kit Guidance from the American Society of Consultant Pharmacists

Question: When is a nurse authorized to remove a controlled drug from an e-kit?

Answer: Controlled drugs in e-boxes are treated the same way as all other controlled drugs. Before a drug can be removed, there must be a valid written prescription (which may be a fax) unless the emergency exception applies. E-boxes should never be used routinely to dispense drugs that should have been reordered. Rather, e-boxes should be used only for unanticipated emergencies that may be a new admission or a new order. Due to the importance of state law in authorizing the use of e-kits in long-term care, it is critical that practitioners, pharmacists and facilities understand all pertinent state laws and regulations governing e-kits, in addition to federal requirements.

Question: What are the potential consequences if nurse take a controlled drug from e-kit before the practitioner has issued a valid prescription?

Answer: Taking possession of a controlled drug without proper authorization can be a serious offense. A nurse who removes a controlled drug from an e-kit without valid authorization may be subject to civil and criminal fines and penalties, disciplinary action by the state licensing board and exclusion from federal health care programs.

Question: Is it permissible for a nurse to remove a controlled drug from an e-kit if s/he has received an oral order from the practitioner?

Answer: Some states permit this practice. However, DEA rules require that the practitioner provide oral authorization or a faxed prescription to the pharmacist before a drug is dispensed. Consequently, a practitioner who gives an oral order to the nurse in the facility by telephone must also ensure that the pharmacy receives either an oral “emergency” order or a written prescription order (which may be sent via facsimile).

Question: Can a nurse remove a CII from an e-kit for a patient who already has a valid prescription for a CII drug but has run out of medication at 2:00 a.m.?

Answer: Assuming this situation meets the criteria for an “emergency situation,” the nurse would need to contact the practitioner for an oral authorization (which must be communicated by the practitioner to the pharmacist, either orally or by fax). While these situations sometimes cannot be avoided, nursing facilities and pharmacies should have systems in place that ensure the timely re-ordering of medications for patients with on-going need for pain management.
Conflicts with Current Utah Statute

The Utah Controlled Substance Act in U.C.A. § 58-37-6 (2)(e); states:

“A separate license is required at each principal place of business or professional practice where the applicant manufactures, produces, distributes, dispenses, conducts research with, or performs laboratory analysis upon controlled substances.”

The Utah Pharmacy Practice Act in U.C.A. § 58-17b-302(3); states:

“Each place of business shall require a separate license. If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.”

Conflicts with Current Utah Administrative Rules


Rule R432-150. Nursing Care Facility.


(1) The facility must provide or obtain by contract routine and emergency drugs, biologicals, and pharmaceutical services to meet resident needs.

(2) The facility must employ or obtain the services of a licensed pharmacist who:

(a) provides consultation on all aspects of pharmacy services in the facility;

(b) establishes a system of records of receipt and disposition of all controlled substances which documents an accurate reconciliation; and

(c) determines that drug records are in order and that an account of all controlled substances is maintained and reconciled monthly.

(3) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(a) The pharmacist must report any irregularities to the attending physician and the director of nursing or health services supervisor.

(b) The physician and the director of Nursing or health services supervisor must indicate acceptance or rejection of the report and document any action taken.

(4) Pharmacy personnel must ensure that labels on drugs and biologicals are in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date.

(5) The facility must store all drugs and biologicals in locked compartments under proper temperature controls according to R432-150-19 (6)(c), and permit only authorized personnel to have access to the keys.
(a) The facility must provide separately locked, permanently affixed compartments for storage of controlled substances listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit dose package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(b) Non-medication materials that are poisonous or caustic may not be stored with medications.

(c) Containers must be clearly labeled.

(d) Medication intended for internal use shall be stored separately from medication intended for external use.

(e) Medications stored at room temperature shall be maintained within 59 and 80 degrees F.

(f) Refrigerated medications shall be maintained within 36 and 46 degrees F.

(6) The facility must maintain an emergency drug supply.

(a) Emergency drug containers shall be sealed to prevent unauthorized use.

(b) Contents of the emergency drug supply must be listed on the outside of the container and the use of contents shall be documented by the nursing staff.

(c) The emergency drug supply shall be stored and located for access by the nursing staff.

(d) The pharmacist must inventory the emergency drug supply monthly.

(e) Used or outdated items shall be replaced within 72 hours by the pharmacist.

(7) The pharmacy must dispense and the facility must ensure that necessary drugs and biologicals are provided on a timely basis.

(8) The facility must limit the duration of a drug order in the absence of the prescriber's specific instructions.

(9) Drug references must be available for all drugs used in the facility. References shall include generic and brand names, available strength and dosage forms, indications and side effects, and other pharmacological data.

(10) Drugs may be sent with the resident upon discharge if so ordered by the discharging physician provided that:

(a) such drugs are released in compliance R156-17a-619; and

(b) a record of the drugs sent with the resident is documented in the resident's health record.

(11) Disposal of controlled substances must be in accordance with the Pharmacy Practice Act.
IMPORTANT POINTS

→ The practice of pharmacy definition and the above described statute prohibit anyone other than a properly licensed pharmacy from possessing stock controlled substances or legend drugs.

→ The Utah Department of Health has invalid and antiquated administrative rules that supersedes what statute does not allow and existing pharmacy law and rule does not even address some of the operating standards mandated by the pharmacist and pharmacy who are providing pharmacy services.

→ As the Federal Register states that emergency kits in Long Term Care Facilities are only viewed as compliant with the Controlled Substance Act IF the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate. The Utah Department of Health is not the appropriate state agency and moreover, the appropriate Utah statute conflicts with the inappropriate state agency administrative rules.

→ Additionally, the existing administrative rules do not define and cover everything mandated in the Federal Register to even be considered compliant.
GUIDELINES FOR HOSPITAL PHARMACIES
and EMERGENCY DEPARTMENT TREATMENT
Approved by the Board of Pharmacy May 21, 2012

The pharmacist is responsible for all pharmacy practice as delineated under Utah Code 58-17b and 58-37f to include:

- ordering, receiving, and stocking;
- filling drug carts, drug rooms, emergency drug stocks;
- controlling inventory, including audit trail for each controlled substance;
- maintaining and adhering to policies and protocols that maintain controls over controlled substances (Utah Controlled Substances Act Subsection R156-37-502 defines unprofessional conduct to include: (4) “failing to maintain controls over controlled substances which would be considered by a prudent practitioner to be effective against diversion, theft, or shortage of controlled substances; (5) being unable to account for shortages of controlled substances for any controlled substance inventory for which the licensee has responsibility.”);
- reviewing Medication Proof of Use forms or logs returned to the pharmacist for purposes of review and reconciliation; and
- submitting all required controlled substance prescription information to the Controlled Substance Database pursuant to Utah Code 58-37f-203.

NOTE: “Responsible” means accountable for. The pharmacist may delegate the task, yet is ultimately accountable for the outcome. Final checks of medications or medication profiles cannot be delegated.

After-hours Medications Taken from Pharmacy When a Pharmacy is Closed

- Only a pharmacist, nurse supervisor, or charge nurse can enter the pharmacy when the pharmacy is closed.
- Medications can only be taken from the pharmacy on an emergency, as needed basis. A medication log must be used to keep a per medication inventory.
- Only a pharmacist, nurse supervisor, or charge nurse can have access and the alarm code to the pharmacy when the pharmacy is closed, although no one but the pharmacist can have a key to the locked controlled substance inventory in the pharmacy. The pharmacy must still be equipped with a security system to permit detection of entry at all times when the facility is closed. An adequate security system for inpatient pharmacies within hospitals would be a system similar to a badge reader access which could uniquely store and retain which authorized person had made entry into the pharmacy after regular hours.
Dispensing of Drugs from an Emergency Room

- Emergency room staff, including the prescribing practitioner or licensed nurse, cannot dispense prescriptions to a patient. The prescribing practitioner can give an emergency supply, which is properly labeled, to a patient to get a patient started on the medication until a pharmacy is open. This is not to be construed to allow a prescribing practitioner to give out an entire prescription amount.

The related community standard for the treatment of typical Emergency Department conditions and STI prophylaxis is seven days.

- Such “emergency doses” of medications shall be labeled with at least:
  - Prescribing practitioner’s name and facility name and telephone number;
  - Patient’s name;
  - Name of medication and strength;
  - Number of tablets given;
  - Date given; and
  - Instructions for use.

- Records of controlled substances dispensed by the prescribing practitioner must be provided to the pharmacy so that applicable prescription data can be reported to the CSD.

NOTE: Physicians may give out “samples” which are clearly marked as a sample “not for resale” until the patient can get to a pharmacy or to try the medication for possible untoward effects. Samples must be dispensed pursuant to Utah Code Annotated § 58-17b-610.

Repackaging:

- It is illegal for retail pharmacies to repackage medications for resale to hospitals, clinics, or other pharmacies. The hospital pharmacy could legally repackage medications for use in its own institution.

Federal Statute:

According to Federal regulations, “repackaging” requires a manufacturer’s license as stated in US Code 21-1300.01(27) and USC 21-1301.11(a).

USC 21-1300.01 reads “Manufacture means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance.”

USC 21-1301.11(a) reads: “Every person who manufactures, distributes, dispenses, imports, or exports any controlled substances or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substances shall obtain a registration.”
CONTROLLED SUBSTANCE DATABASE MODIFICATIONS

2014 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Bradley G. Last

LONG TITLE

General Description:
This bill modifies the Controlled Substance Database Act regarding access by pharmacy technicians.

Highlighted Provisions:
This bill:
> allows the pharmacist-in-charge to designate a licensed pharmacy technician to have access to the database on behalf of the pharmacist in accordance with statutory requirements.

Money Appropriated in this Bill:
None

Other Special Clauses:
None

Utah Code Sections Affected:
AMENDS:
58-37f-301, as last amended by Laws of Utah 2013, Chapters 12, 130, and 262

Be it enacted by the Legislature of the state of Utah:
Section 1. Section 58-37f-301 is amended to read:
(1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
(A) fit within the responsibilities of the Department of Health for health and welfare;
(B) are reviewed and approved by an Institutional Review Board that is approved for
human subject research by the United States Department of Health and Human Services; and
(C) are not conducted for profit or commercial gain; and
(D) are conducted in a research facility, as defined by division rule, that is associated
with a university or college in the state accredited by the Northwest Commission on Colleges
and Universities;
(iii) the designee protects the information as a business associate of the Department of
Health; and
(iv) the identity of the prescribers, patients, and pharmacies in the database are
de-identified, confidential, not disclosed in any manner to the designee or to any individual
who is not directly involved in the scientific studies;
(e) a licensed practitioner having authority to prescribe controlled substances, to the
extent the information:
(i) (A) relates specifically to a current or prospective patient of the practitioner; and
(B) is provided to or sought by the practitioner for the purpose of:
(I) prescribing or considering prescribing any controlled substance to the current or
prospective patient;
(II) diagnosing the current or prospective patient;
(III) providing medical treatment or medical advice to the current or prospective
patient; or
(IV) determining whether the current or prospective patient:
(A) is attempting to fraudulently obtain a controlled substance from the practitioner;
or
(B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled
substance from the practitioner;
(ii) (A) relates specifically to a former patient of the practitioner; and
(B) is provided to or sought by the practitioner for the purpose of determining whether
the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a
controlled substance from the practitioner;
(iii) relates specifically to an individual who has access to the practitioner's Drug
(h) a licensed pharmacist having authority to dispense a controlled substance to the extent the information is provided or sought for the purpose of:

(i) dispensing or considering dispensing any controlled substance; or

(ii) determining whether a person:

(A) is attempting to fraudulently obtain a controlled substance from the pharmacist; or

(B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled substance from the pharmacist;

(i) in accordance with Subsection (3)(a), a licensed pharmacy technician who is an employee of a pharmacy as defined in Section 58-17b-102, for the purposes described in Subsection (2)(h)(i) or (ii), if:

(i) the employee is designated by the pharmacist-in-charge as an individual authorized to access the information on behalf of a licensed pharmacist employed by the pharmacy;

(ii) the pharmacist-in-charge provides written notice to the division of the identity of the employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee;

(f) federal, state, and local law enforcement authorities, and state and local prosecutors, engaged as a specified duty of their employment in enforcing laws:

(i) regulating controlled substances;

(ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; or

(iii) providing information about a criminal defendant to defense counsel, upon request during the discovery process, for the purpose of establishing a defense in a criminal case;

(k) employees of the Office of Internal Audit and Program Integrity within the Department of Health who are engaged in their specified duty of ensuring Medicaid program integrity under Section 26-18-2.3;

(l) a mental health therapist, if:

(i) the information relates to a patient who is:
designated under Subsection (2)(f), (2)(g), or (4)(c) should be granted access to the database;

and

(ii) establish the information to be provided by an emergency room employee under Subsection (4).

(c) The division shall grant an employee designated under Subsection (2)(f), (2)(g), or (4)(c) access to the database, unless the division determines, based on a background check, that the employee poses a security risk to the information contained in the database.

(4) (a) An individual who is employed in the emergency room of a hospital may exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if the individual is designated under Subsection (4)(c) and the licensed practitioner:

(i) is employed in the emergency room;

(ii) is treating an emergency room patient for an emergency medical condition; and

(iii) requests that an individual employed in the emergency room and designated under Subsection (4)(c) obtain information regarding the patient from the database as needed in the course of treatment.

(b) The emergency room employee obtaining information from the database shall, when gaining access to the database, provide to the database the name and any additional identifiers regarding the requesting practitioner as required by division administrative rule established under Subsection (3)(b).

(c) An individual employed in the emergency room under this Subsection (4) may obtain information from the database as provided in Subsection (4)(a) if:

(i) the employee is designated by the practitioner as an individual authorized to access the information on behalf of the practitioner;

(ii) the practitioner and the hospital operating the emergency room provide written notice to the division of the identity of the designated employee; and

(iii) the division:

(A) grants the employee access to the database; and

(B) provides the employee with a password that is unique to that employee to access the database in order to permit the division to comply with the requirements of Subsection 58-37f-203(3)(b) with respect to the employee.

(d) The division may impose a fee, in accordance with Section 63J-1-504, on a
Senator Evan J. Vickers proposes the following substitute bill:

**PHARMACEUTICAL DISPENSING AMENDMENTS**

2014 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Stewart Barlow

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act to create a dispensing medical practitioner license and a license classification for a dispensing medical practitioner clinic pharmacy.

Highlighted Provisions:

This bill:

- defines terms;
- establishes the license classification "dispensing medical practitioner" under the Pharmacy Practice Act for medical practitioners who prescribe and dispense a drug;
- establishes the pharmacy facility license classification "dispensing medical practitioner clinic pharmacy" under the Pharmacy Practice Act;
- creates Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy;
- removes the exemption from the Pharmacy Practice Act for medical practitioners who prescribe and dispense a cosmetic drug, injectable weight loss drug, or a cancer drug treatment regimen;
- requires a license as a dispensing medical practitioner for a health care practitioner to dispense:
Section 8. Section 58-17b-802 is enacted to read:

**58-17b-802. Definitions.**

As used in this part:

(1) (a) "Cosmetic drug" means a prescription drug that:

(i) is for the purpose of promoting attractiveness or altering the appearance of an individual; and

(ii) (A) is listed as a cosmetic drug subject to the exemption under this section by the division by administrative rule; or

(B) has been expressly approved for online dispensing, whether or not it is dispensed online or through a physician's office.

(b) "Cosmetic drug" does not include a prescription drug that is:

(i) a controlled substance;

(ii) compounded by the physician; or

(iii) prescribed or used for the patient for the purpose of diagnosing, curing, or preventing a disease.

(2) "Employer sponsored clinic" means an entity that has a medical director who is licensed as a physician as defined in Section 58-67-102 and offers health care only to the employees of an exclusive group of employers and the employees' dependents.

(3) "Health care" is as defined in Section 31A-1-301

(4) (a) "Injectable weight loss drug" means an injectable prescription drug:

(i) prescribed to promote weight loss; and

(ii) listed as an injectable prescription drug subject to exemption under this section by the division by administrative rule.

(b) "Injectable weight loss drug" does not include a prescription drug that is a controlled substance.

(5) "Prepackaged drug" means a prescription drug that:

(a) is not listed under federal or state law as a Schedule I, II, III, IV, or V drug; and

(b) is packaged in a fixed quantity per package by:

(i) the drug manufacturer;

(ii) a pharmaceutical wholesaler or distributor; or

(iii) a pharmacy licensed under this title.
Section 9. Section 58-17b-803 is enacted to read:

58-17b-803. Qualifications for licensure as a dispensing medical practitioner -- Scope of practice.

(1) An applicant for a license as a dispensing medical practitioner shall:
   (a) be licensed in good standing under at least one of the chapters listed in Subsection 58-17b-102(23)(a); and
   (b) submit an application for a license as a dispensing medical practitioner in a form prescribed by the division and pay a fee established by the division.

(2) The division shall accept the licensing in good standing under Subsection (1) in lieu of requiring an applicant for a license under this part to comply with Sections 58-17b-303 and 58-17b-307.

(3) A dispensing medical practitioner may dispense, in accordance with this part:
   (a) a cosmetic drug and an injectable weight loss drug if:
      (i) the drug was prescribed by the dispensing medical practitioner to the dispensing medical practitioner's patient; and
      (ii) the dispensing medical practitioner complies with administrative rules adopted by the division under Subsection 58-17b-802(1);
   (b) a cancer drug treatment regimen if the dispensing medical practitioner complies with Section 58-17b-805; and
   (c) a pre-packaged drug to an employee or a dependent of an employee at an employer sponsored clinic if the dispensing medical practitioner:
      (i) treats an employee, or the dependent of an employee, of one of an exclusive group of employers at an employer sponsored clinic;
      (ii) prescribes a prepackaged drug to the employee or the employee's dependent;
      (iii) dispenses the prepackaged drug at the employer sponsored clinic; and
      (iv) complies with administrative rules adopted by the Board of Pharmacy that establish labeling, record keeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements.

(4) A dispensing medical practitioner:
   (a) shall inform the patient:
      (i) that the drug dispensed by the practitioner may be obtained from a pharmacy
section 13. Section 58-31b-502 is amended to read:


"Unprofessional conduct" includes:

(1) failure to safeguard a patient's right to privacy as to the patient's person, condition, diagnosis, personal effects, or any other matter about which the licensee is privileged to know because of the licensee's or person with a certification's position or practice as a nurse or practice as a medication aide certified;

(2) failure to provide nursing service or service as a medication aide certified in a manner that demonstrates respect for the patient's human dignity and unique personal character and needs without regard to the patient's race, religion, ethnic background, socioeconomic status, age, sex, or the nature of the patient's health problem;

(3) engaging in sexual relations with a patient during any:

(a) period when a generally recognized professional relationship exists between the person licensed or certified under this chapter and patient; or

(b) extended period when a patient has reasonable cause to believe a professional relationship exists between the person licensed or certified under the provisions of this chapter
CONTROLLED SUBSTANCES ACT AMENDMENTS

2014 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Stewart Barlow

LONG TITLE

General Description:
This bill modifies the Utah Controlled Substances Act regarding prescriptions for controlled substances.

Highlighted Provisions:
This bill:
• provides that more than one controlled substance may be included in a prescription.

Money Appropriated in this Bill:
None

Other Special Clauses:
None

Utah Code Sections Affected:
AMENDS:
58-37-6, as last amended by Laws of Utah 2012, Chapter 272

Be it enacted by the Legislature of the state of Utah:
Section 1. Section 58-37-6 is amended to read:
58-37-6. License to manufacture, produce, distribute, dispense, administer, or conduct research -- Issuance by division -- Denial, suspension, or revocation -- Records required -- Prescriptions.
(1) (a) The division may adopt rules relating to the licensing and control of the
the prescribed controlled substance is to be used in research.

(f) Except when administered directly to an ultimate user by a licensed practitioner, controlled substances are subject to the following restrictions:

(i) (A) A prescription for a Schedule II substance may not be refilled.

(B) A Schedule II controlled substance may not be filled in a quantity to exceed a one-month's supply, as directed on the daily dosage rate of the prescriptions.

(ii) A Schedule III or IV controlled substance may be filled only within six months of issuance, and may not be refilled more than six months after the date of its original issuance or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(iii) All other controlled substances in Schedule V may be refilled as the prescriber's prescription directs, but they may not be refilled one year after the date the prescription was issued unless renewed by the practitioner.

(iv) Any prescription for a Schedule II substance may not be dispensed if it is not presented to a pharmacist for dispensing by a pharmacist or a pharmacy intern within 30 days after the date the prescription was issued, or 30 days after the dispensing date, if that date is specified separately from the date of issue.

(v) A practitioner may issue more than one prescription at the same time for the same Schedule II controlled substance, but only under the following conditions:

(A) no more than three prescriptions for the same Schedule II controlled substance may be issued at the same time;

(B) no one prescription may exceed a 30-day supply;

(C) a second or third prescription shall include the date of issuance and the date for dispensing; and

(D) unless the practitioner determines there is a valid medical reason to the contrary, the date for dispensing a second or third prescription may not be fewer than 30 days from the dispensing date of the previous prescription.

[(vi) Each prescription for a controlled substance may contain only one controlled substance per prescription form and may not contain any other legend drug or prescription item:]

(g) An order for a controlled substance in Schedules II through V for use by an
MAIL-ORDER WHOLESALE DRUG AMENDMENTS

2014 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Stewart Barlow

Senate Sponsor: ____________

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act.

Highlighted Provisions:

This bill:

- amends the definition of a class C pharmacy subject to regulation under the
  Pharmacy Practice Act.

Money Appropriated in this Bill:

None

Other Special Clauses:

This bill takes effect on July 1, 2014.

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2013, Chapters 52, 166, and 423

Be it enacted by the Legislature of the state of Utah:

Section 1. Section 58-17b-102 is amended to read:

58-17b-102. Definitions.

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

(1) "Administering" means:

(a) the direct application of a prescription drug or device, whether by injection,
(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 located in Utah that is authorized to engage 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) "Closed-door pharmacy" means a pharmacy that 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, but not including 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
and

(b) are supervised by a pharmacist in accordance with rules adopted by the division in collaboration with the board.

(67) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

(68) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

(69) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.

Section 2. Effective date.

This bill takes effect on July 1, 2014.
EMployer Sponsored Clinic - Prescription Drug

Amendments

2014 General Session

State of Utah

Chief Sponsor: Stewart Barlow

Senate Sponsor: 

Long Title

General Description:

This bill amends the Pharmacy Practice Act to exempt a prescribing practitioner from its licensing requirements under certain circumstances.

Highlighted Provisions:

This bill:

- exempts a prescribing practitioner from the licensing requirements of the Pharmacy Practice Act if the prescribing practitioner dispenses a prepackaged drug at an employer sponsored clinic and complies with other requirements;
- repeals, subject to sunset review, the provisions of this bill relating to the exemption described above; and
- makes technical and conforming changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-301, as last amended by Laws of Utah 2013, Chapter 52

58-17b-302, as last amended by Laws of Utah 2013, Chapter 52
Be it enacted by the Legislature of the state of Utah:

Section 1. Section 58-17b-301 is amended to read:

58-17b-301. License required -- License classifications for individuals.

(1) A license is required to engage in the practice of pharmacy, telepharmacy, or the practice of a pharmacy technician, except as specifically provided in Section 58-1-307, 58-17b-309, [or] 58-17b-309.5, 58-17-309.6, or 58-17b-309.7.

(2) The division shall issue to an individual who qualifies under this chapter a license in the classification of:

(a) pharmacist;
(b) pharmacy intern; or
(c) pharmacy technician.

Section 2. Section 58-17b-302 is amended to read:

58-17b-302. License required -- License classifications for pharmacy facilities.

(1) A license is required to act as a pharmacy, except as specifically exempted from licensure under Section 58-1-307 [or], 58-17b-309, 58-17b-309.5, 58-17-309.6, or 58-17b-309.7.

(2) The division shall issue a pharmacy license to a facility that qualifies under this chapter in the classification of a:

(a) class A pharmacy;
(b) class B pharmacy;
(c) class C pharmacy;
(d) class D pharmacy; or
(e) class E pharmacy.

(3) Each place of business shall require a separate license. If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.
(4) The division may further define or supplement the classifications of pharmacies.

The division may impose restrictions upon classifications to protect the public health, safety, and welfare.

(5) Each pharmacy shall have a pharmacist-in-charge, except as otherwise provided by rule.

(6) Whenever an applicable statute or rule requires or prohibits action by a pharmacy, the pharmacist-in-charge and the owner of the pharmacy shall be responsible for all activities of the pharmacy, regardless of the form of the business organization.

Section 3. Section 58-17b-309 is amended to read:

58-17b-309. Exemptions from licensure.

(1) As used in this section:

(a) "Cosmetic drug":

(i) means a prescription drug that is:

(A) for the purpose of promoting attractiveness or altering the appearance of an individual; and

(B) listed as a cosmetic drug subject to the exemption under this section by the division by administrative rule or has been expressly approved for online dispensing, whether or not it is dispensed online or through a physician's office; and

(ii) does not include a prescription drug that is:

(A) a controlled substance;

(B) compounded by the physician; or

(C) prescribed or used for the patient for the purpose of diagnosing, curing, or preventing a disease.

(b) "Injectable weight loss drug":

(i) means an injectable prescription drug:

(A) prescribed to promote weight loss; and

(B) listed as an injectable prescription drug subject to exemption under this section by the division by administrative rule; and

(ii) does not include a prescription drug that is a controlled substance.

(c) "Prescribing practitioner" means an individual licensed under:

(i) Chapter 31b, Nurse Practice Act, as an advanced practice registered nurse with
prescriptive practice;
   (ii) Chapter 67, Utah Medical Practice Act;
   (iii) Chapter 68, Utah Osteopathic Medical Practice Act; or
   (iv) Chapter 70a, Physician Assistant Act.
(2) In addition to the exemptions from licensure in Sections 58-1-307 [and] 58-17b-309.5, 58-17b-309.6, and 58-17b-309.7, the following individuals may engage in the acts or practices described in this section without being licensed under this chapter:
   (a) [if the] an individual [is] described in Subsections (2)(b), (d), or (e), if the individual notifies the division in writing of the individual’s intent to dispense a drug under this [subsection] Subsection (2);
   (b) a person selling or providing contact lenses in accordance with Section 58-16a-801;
   (c) an individual engaging in the practice of pharmacy technician under the direct personal supervision of a pharmacist while making satisfactory progress in an approved program as defined in division rule;
   (d) a prescribing practitioner who prescribes and dispenses a cosmetic drug or an injectable weight loss drug to the prescribing practitioner’s patient in accordance with Subsection (4); or
   (e) an optometrist, as defined in Section 58-16a-101, acting within the optometrist’s scope of practice as defined in Section 58-16a-601, who prescribes and dispenses a cosmetic drug to the optometrist’s patient in accordance with Subsection (4).
(3) In accordance with Subsection 58-1-303(1)(a), an individual exempt under Subsection (2)(c) must take all examinations as required by division rule following completion of an approved curriculum of education, within the required time frame. This exemption expires immediately upon notification of a failing score of an examination, and the individual may not continue working as a pharmacy technician even under direct supervision.
(4) A prescribing practitioner or optometrist is exempt from licensing under the provisions of this part if the prescribing practitioner or optometrist:
   (a) (i) writes a prescription for a drug the prescribing practitioner or optometrist has the authority to dispense under Subsection (4)(b); and
   (ii) informs the patient:
   (A) that the prescription may be filled at a pharmacy or dispensed in the prescribing
prescribing practitioner or optometrist consents to the jurisdiction of the division to inspect the
designating practitioner's or optometrist's office and determine if the provisions of this section
are being met by the prescribing practitioner or optometrist.
(d) If a prescribing practitioner or optometrist violates a provision of this section, the
prescribing practitioner or optometrist may be subject to discipline under:
(i) this chapter; and
(ii) (A) Chapter 16a, Utah Optometry Practice Act;
(B) Chapter 31b, Nurse Practice Act;
(C) Chapter 67, Utah Medical Practice Act;
(D) Chapter 68, Utah Osteopathic Medical Practice Act;
(E) Chapter 70a, Physician Assistant Act; or
(F) Chapter 83, Online Prescribing, Dispensing, and Facilitation Licensing Act.
(6) Except as provided in Subsection (2)(e), this section does not restrict or limit the
scope of practice of an optometrist or optometric physician licensed under Chapter 16a, Utah
Optometry Practice Act.
Section 4. Section 58-17b-309.5 is amended to read:
58-17b-309.5. Exemption for prescribing practitioner of cancer drug regimen --
Division study of dispensing practitioners.
(1) [For purposes of] As used in this section, "cancer drug treatment regimen":
(a) means a prescription drug used to treat cancer, manage its symptoms, or provide
continuity of care for a cancer patient;
(b) includes:
(i) a chemotherapy drug administered intravenously, orally, rectally, or by dermal
methods; and
(ii) a drug used to support cancer treatment, including to treat, alleviate, or minimize
physical and psychological symptoms or pain, or to improve patient tolerance of cancer
treatments or prepare a patient for a subsequent course of therapy; and
(c) does not mean a drug listed under federal law as a Schedule I, II, or III drug.
(2) In addition to the [exemption] exemptions from licensure under [Section] Sections
58-1-307, 58-17b-309.5, 58-17b-309.6, and 58-17b-309.7, the following individuals are exempt
from licensure under this chapter:
(ii) is acting under the direction of a prescribing practitioner who is immediately available on site for any necessary consultation, and who has complied with Subsection (2)(b)(i);

(iii) prepares or provides the cancer drug treatment regimen to the patient at the outpatient clinic setting; and

(iv) follows Subsections (2)(b)(iv), (v), and (vii).

(3) (a) The division shall work with stakeholders to evaluate the exemptions to licensure under this title in Subsections 58-17b-309(2)(b), (d), and (e) and this section.

(b) The evaluation under this Subsection (3) shall include:

(i) practitioner compliance with the requirements of this section and Section 58-17b-309;

(ii) current research on dispensing and patient safety;

(iii) survey of other state dispensing laws; and

(iv) recommendations for future action concerning practitioner dispensing.

(c) The division shall report to the Legislature's Health and Human Services Interim Committee by November 30, 2012, and by November 30, 2013, with the results and recommendations from the evaluation required by this Subsection (3).

(4) This section sunsets in accordance with Section 631-1-258.

Section 5. Section 58-17b-309.7 is enacted to read:

58-17b-309.7. Exemption for a practitioner prescribing prepackaged drugs at an employer sponsored clinic.

(1) As used in this section:

(a) "Employer sponsored clinic" means an entity that offers health care only to the employees of an exclusive group of employers and the employees' dependents.

(b) "Health care" is as defined in Section 31A-1-301.

(c) "Prepackaged drug" means a prescription drug that:

(i) is not listed under federal or state law as a Schedule I, II, III, IV, or V drug; and

(ii) is packaged in a fixed quantity per package by:

(A) the drug manufacturer;

(B) a pharmaceutical wholesaler or distributor; or

(C) a pharmacy licensed under this title.
(d) "Prescribing practitioner" is as defined in Section 58-17b-309.

(2) In addition to the exemptions described in Sections 58-1-307, 58-17b-309,
58-17b-309.5, and 58-17b-309.6, a prescribing practitioner is exempt from the licensing
requirements of this chapter if the prescribing practitioner:

(a) treats an employee of one of an exclusive group of employers at an employer
sponsored clinic;

(b) prescribes a prepackaged drug to the employee;

(c) dispenses the prepackaged drug at the employer sponsored clinic;

(d) notifies the division:

(i) that the prescribing practitioner intends to dispense the prepackaged drug at the
employer sponsored clinic; and

(ii) of the drug the prescribing practitioner intends to dispense;

(e) determines that providing the prepackaged drug to the employee at the employer
sponsored clinic is in the employee's best interest;

(f) informs the employee:

(i) that the employee may obtain the drug prescribed by the prescribing practitioner
from a pharmacy that is unaffiliated with the prescribing practitioner;

(ii) of the directions for appropriate use of the prepackaged drug;

(iii) of potential side effects to the use of the prepackaged drug; and

(iv) how to contact the prescribing practitioner if the employee has questions or
concerns regarding the drug;

(g) offers the employee the opportunity to consult with a pharmacist if the employee
asks for patient counseling; and

(h) follows the administrative rules for a prescribing practitioner at an employer
sponsored clinic established by the division under Subsection (4).

(3) If the chapter that governs the license of a prescribing practitioner dispensing a
prepackaged drug under this section requires physician supervision in its scope of practice
requirements, the prescribing practitioner shall only dispense a prepackaged drug under the
supervision of an individual licensed under Chapter 67, Utah Medical Practice Act, or Chapter
68, Utah Osteopathic Medical Practice Act.

(4) The division shall, in consultation with the board of pharmacy and the Physicians
Licensing Board created in Section 58-67-201, adopt administrative rules pursuant to Title 63G, Chapter 3, Utah Administrative Rulemaking Act, that establish labeling, record keeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements for a prescribing practitioner at an employer sponsored clinic.

(5) The division may inspect the office of a prescribing practitioner who is dispensing a prepackaged drug at an employer sponsored clinic to determine whether the prescribing practitioner is in compliance with this section.

(6) If a prescribing practitioner violates a provision of this section, the prescribing practitioner may be subject to discipline under:

(a) this chapter; and

(b) any other chapter that governs the terms of the prescribing practitioner's license.

(7) The division shall evaluate the exemption created by this section and report to the Legislature's Health and Human Services Interim Committee by July 1, 2016, and by July 1, 2018, on the results of the evaluation and the division's recommendations regarding the exemption.

Section 6. Section 631-1-258 is amended to read:

631-1-258. Repeal dates, Title 58.

(1) Title 58, Chapter 13, Health Care Providers Immunity from Liability Act, is repealed July 1, 2016.

(2) Title 58, Chapter 15, Health Facility Administrator Act, is repealed July 1, 2015.

(3) Section 58-17b-309.5 is repealed July 1, 2015.

(4) Section 58-17b-309.7 is repealed on July 1, 2018.

(5) Title 58, Chapter 20a, Environmental Health Scientist Act, is repealed July 1, 2018.

(6) Title 58, Chapter 40, Recreational Therapy Practice Act, is repealed July 1, 2023.

(7) Title 58, Chapter 41, Speech-language Pathology and Audiology Licensing Act, is repealed July 1, 2019.

(8) Title 58, Chapter 42a, Occupational Therapy Practice Act, is repealed July 1, 2015.

(9) Title 58, Chapter 46a, Hearing Instrument Specialist Licensing Act, is
repealed July 1, 2023.

Title 58, Chapter 47b, Massage Therapy Practice Act, is repealed July 1, 2014.

Section 58-69-302.5 is repealed on July 1, 2015.

Title 58, Chapter 72, Acupuncture Licensing Act, is repealed July 1, 2017.

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Office of Legislative Research and General Counsel