

Pharmacy Board Report
November 2013

#1

	January-Oct 2013	Nov-13
Administrative Filings	29	6
Criminal Filing/Felony	3	
Letter of Concern	46	8
PR/Outreach	2	1
Cases Received	655	27
Case Assigned	624	26
Closed Cases	647	46
Citations Issued	95	3
Pharmacy Inspections	187	24
Pharmacy Alerts	160	27
Dr. Shopper/Law Enforcement Letters	110	76

NOTES:

Nov-13

Pharmacy Group

The Pharmacy Group is currently re-designing the Self Inspection Forms to be more user friendly. They hope to have them sent to Class A Pharmacies by the middle of January 2014.

**USP <795> Guidelines
For Standard Operating Procedures
DRAFT 12/17/2013**

As defined in USP <795>, any pharmacy that engages in the practice of compounding is required to have Standard Operating Procedures (SOP) in place to state how different areas of practice are handled. The following document is designed to be a guideline to aid pharmacies in producing their own SOP's to be compliant with state law. The items on this checklist should be included in the SOP. This is a guideline, not all inclusive. Pharmacies should write their SOP with their own practice in mind.

Patient Counseling of Compounded Medications:

- Procedure to educate patient and/or caregiver on how to use the compounded preparation.
- Includes storage, handling, and disposal of preparations; potential adverse effects and any other information deemed necessary
- Procedure in effect to report any changes in preparations, adverse side effects, etc. reported by patient. Includes investigation and reporting to proper authorities.
- Procedure for recall of compounded preparations

Quality Control

Compounding pharmacies must have a documented quality control plan that contains the following:

- Observation of the finished product, documenting any discrepancies and the corrective action taken
- The Master Formulation Record, the Compounding Record and associated written procedures shall be followed in execution of the compounding process. Any deviation shall be documented.
- Check and recheck each procedure at each stage of the process will be documented
- Have written procedures that describe the tests or examinations conducted on the compounded preparations,
- Control procedures shall be established to monitor the output and verify performance of compounding equipment

Compounding Documentation

There are specific documentation requirements for compounding. These are the Master Formulation Record and the Compounding Record. Both of these are required to be retained for the same length of time that a prescription hard copy would be required to be retained.

Master Formulation Record:

□The Master Formulation Record (MFR) shall contain the following information:

1. The name, strength and dosage form of the preparation
2. Calculations required to determine and verify quantities of components and doses of active pharmaceutical ingredients.
3. Description of all ingredients and their quantities
4. Compatibility and stability information, including references if appropriate.
5. Equipment required to prepare preparation
6. Detailed mixing instructions
7. Sample labeling information, including, generic name and quantity or concentration of each active ingredient, assigned BUD, storage conditions, and prescription or control number
8. Container used in dispensing
9. Packaging and storage requirements
10. Description of final preparation
11. Quality control measures and expected results

Compounding Record

□The Compounding Record (CR) shall contain the following information:

1. The name, strength and dosage form of the preparation
2. MFR reference for the preparation
3. Names and quantities of all components
4. Source, lot numbers, and expiration dates of components
5. Total quantity compounded
6. Name of person(s) who prepared the preparation, who performed the quality control procedures, and who approved the preparation
7. Date of preparation
8. Assigned control or RX number
9. Assigned BUD
10. Duplicate label as described in the MFR
11. Description of final preparation

12. Results of quality control procedures
13. Documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver.

Packaging and Drug Preparation Containers

Procedure that ensures the compounder understands the importance of containers used to package compounded medications:

- Utilize packaging that meets USP requirements and be familiar with the USP standards for containers used to package compounded preparations.
- The container used depends on the physical and chemical properties of the compounded preparation. Compounders should consider container drug interactions for substances that have absorptive or leaching properties.
- Containers and closures are stored off the floor
- Containers are rotated so that the oldest stock is used first.

Animal Patients

Animal patient must be identified as either companion animal or food animal.

- Documentation of Withdrawal Time (WDT) if patient is a food animal. The WDT must be on the label of the preparation.
- Be knowledgeable about physiology, metabolic toxicity of medications for each species
- Document compliance with all state and federal laws regarding drug use in animals.

Component Selection, handling and Storage

- Documentation of sourcing for components that are USP, NF, FCC
- Component expiration dates may be honored if the following are met:
 - Stored in original container under recommended conditions
 - Minimal exposure from opening/closing container
 - Withdrawals performed by trained individuals
- Document expiration of components, using the following as guidelines
 - Components moved to new containers have the following documentation:
 - component name
 - Original supplier
 - Lot or control number
 - Transfer date
 - Expiration date

- Components without expiration dates are given conservative dates no more than three years from the date received
 - Manufactured drugs must be from an FDA registered facility and have expiration/lot on the label
- Guidelines for component selection
 - When using manufactured drugs, consider all components of that product and not just the active ingredient to determine therapeutic appropriateness and stability
 - When preparing dietary or nutritional supplements, use USP, NF, or FCC products when available. If unavailable, products with a food grade standard and a proven record of safety in humans should be used
 - Components from ruminant animal require the supplier to provide written assurance the product is compliant with all regulations
 - Be aware of components that have been removed from the market by the FDA for efficacy reasons
- Store everything according to storage suggestions from the manufacturer
 - Clean area
 - Appropriate temperature and humidity
 - Off the floor
 - Rotated (old to new)
 - Labeled

Compounding Process

Pharmacy should have a designated compounding area

- Pharmacy personnel authorized to be in compounding area
- Technique for working in the designated compounding area and behaviors to avoid.
- Personal hygiene

Beyond Use Date

Each preparation dispensed must have a Beyond Use Date (BUD) on the label

- The following are the BUD guidelines from USP <795>
 - Non-aqueous formulation- 6 months
 - Water containing non-oral – 30 days
 - Water containing oral – 14 days, refrigerated
- All formulas need a source for BUD. If using one from above, cite USP 795. Otherwise, the source must be cited

- BUD cannot be later than the earliest expiration date of the Active Pharmaceutical Ingredient (API)
- If a pharmacist feels that BUD for a particular product are inadequate, they may use professional judgment to assign a different BUD. However, they must be prepared to defend that judgment.

3a

**Pharmacy Practice Act Rule
R156-17b-610. Operating Standards - Patient Counseling.**

In accordance with Subsection 58-17b-601(1), guidelines for providing patient counseling established in Section 58-17b-613 include the following:

(1) Counseling shall be offered orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibit such oral communication.

(2) A pharmacy facility shall orally offer counsel but shall not be required to provide counsel to a patient or patient's agent when the patient or patient's agent refuses such consultation.

~~[(1)]~~ 3 Based upon the pharmacist's or pharmacy intern's professional judgment, patient counseling may be discussed to include the following elements:

- (a) the name and description of the prescription drug;
- (b) the dosage form, dose, route of administration and duration of drug therapy;
- (c) intended use of the drug, when known, and expected action;
- (d) special directions and precautions for preparation, administration and use by the patient;
- (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (f) techniques for self-monitoring drug therapy;
- (g) proper storage;
- (h) prescription refill information;
- (i) action to be taken in the event of a missed dose;
- (j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and
- (k) the date after which the prescription should not be taken or used, or the beyond use date.

~~[(2) Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.~~

~~(3) A pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.]~~

(4) The offer to counsel shall be documented and said documentation shall be available to the Division. These records shall be maintained for a period of five years and be available for inspection within 7-10 business days.

~~[(5) Counseling shall be:~~

- ~~(a) provided with each new prescription drug order, once yearly on maintenance medications, and if the pharmacist deems appropriate with prescription drug refills;~~
- ~~(b) provided offered for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent; and~~
- ~~(c) communicated verbally in person unless the patient or the patient's agent is not at the pharmacy or a specific communication barrier prohibits such verbal communication.]~~

~~[(6)]~~ 5 Only a pharmacist or pharmacy intern may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs.

~~[(7)]~~ 6 ~~[In addition to the requirements of Subsections (1) through (6) of this section, i]~~ If a prescription drug order is delivered to the patient at the pharmacy, a filled prescription may not be delivered to a patient unless a pharmacist is in the pharmacy.

However, an agent of the pharmacist may deliver a prescription drug order to the patient or the patient's agent if the pharmacist is absent for ten minutes or less and provided a record of the delivery is maintained and contains the following information:

- (a) date of the delivery;
- (b) unique identification number of the prescription drug order;
- (c) patient's name;
- (d) patient's phone number or the phone number of the person picking up the prescription; and
- (e) signature of the person picking up the prescription.

([8]7) If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable:

- (a) the information specified in Subsection (1) of this section shall be delivered with the dispensed prescription in writing;
- (b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and
- (c) written information provided in Subsection (8)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

(8) Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

58-17b-613. Patient counseling.

- (1) Every pharmacy facility shall orally offer to counsel a patient or a patient's agent in a personal face-to-face discussion with respect to each prescription drug dispensed, if the patient or patient's agent:
- (a) delivers the prescription in person to the pharmacist or pharmacy intern; or
 - (b) receives the drug in person at the time it is dispensed at the pharmacy facility.
- (2) A pharmacist or pharmacy intern shall provide counseling to each patient, and shall provide the patient with a toll-free telephone number by which the patient may contact a pharmacist at the dispensing pharmacy during normal business hours and receive oral counseling, with respect to each prescription drug dispensed if the patient provides or the prescription is otherwise provided to the pharmacy facility by a means other than personal delivery, and the dispensed prescription drug is mailed or otherwise delivered to the patient outside of the pharmacy facility.
- (3) (a) The provisions of Subsections (1) and (2) do not apply to incarcerated patients or persons otherwise under the jurisdiction of the Utah Department of Corrections or a county detention facility.
- (b) A written communication with a person described in Subsection (3)(a) shall be used by a pharmacist or pharmacy intern in lieu of a face to face or telephonic communication for the purpose of counseling the patient.

BRICK

MAIL
ORDER

PRISON

R156-17b-303b. Licensure - Pharmacist - Pharmacy Internship Standards.

(1) In accordance with Subsection 58-17b-303(1)(g), the standards for the pharmacy internship required for licensure as a pharmacist is established as one of the following:

(a) for graduates of all U.S. [~~and foreign~~] pharmacy schools, include the following:

X ([a]i) At least 1740 hours of practice supervised by a pharmacy preceptor shall be obtained in Utah or another state or territory of the United States, or a combination of both according to the Accreditation Council for Pharmacy Education (ACPE), Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree Guidelines Version 2.0 Effective February 14, 2001, which is hereby incorporated by reference.

X ([i]A) Introductory pharmacy practice experiences (IPPE) shall account for not less than 300 hours over the first three professional years.

X ([ii]B) A minimum of 150 hours shall be balanced between community pharmacy and institutional health system settings.

✓ ([iii]C) Advanced pharmacy practice experiences (APPE) shall include at least 1440 hours (i.e., 36 weeks) during the last academic year and after all IPPE requirements are completed.

✓ ([iv]D) Required experiences shall:

✓ (A) include primary, acute, chronic, and preventive care among patients of all ages; and

✓ (B) develop pharmacist-delivered patient care competencies in the community pharmacy, hospital or health-system pharmacy, ambulatory care, inpatient/acute care, and general medicine settings.

✓ (v) Internship hours completed in another state or territory of the United States shall be accepted based on the approval of the hours by the pharmacy board in the jurisdiction where the hours were obtained.

✓ (b) Evidence of completed internship hours shall be documented to the Division by the pharmacy intern at the time application is made for a Utah pharmacist license.

✓ (c) Pharmacy interns participating in internships may be credited no more than 50 hours per week of internship experience.

✓ (d) No credit will be awarded for didactic experience.

X (2) If a pharmacy intern is suspended or dismissed from an approved College of Pharmacy, the intern shall notify the Division within 15 days of the suspension or dismissal.

✓ (3) If a pharmacy intern ceases to meet all requirements for intern licensure, the pharmacy intern shall surrender the pharmacy intern license to the Division within 60 days unless an extension is requested and granted by the Division in collaboration with the Board.

3c

R156-17b-614a. Operating Standards - Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), standards for the operations for a Class A and Class B pharmacy include:

(a) shall be well lighted, well ventilated, clean and sanitary;

(b) the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;

(c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;

(d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;

(e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and

(f) be equipped with a security system to:

(i) permit detection of entry at all times when the facility is closed[-]; and

(ii) provide notice of unauthorized entry to an individual who is able to respond quickly and reasonably assess the entry and resolve the matter

R156-17b-601. Operating Standards - Pharmacy Technician.

In accordance with Subsection 58-17b-102(~~54~~53), practice as a licensed pharmacy technician is defined as follows:

(1) The pharmacy technician may perform any task associated with the physical preparation and processing of prescription and medication orders including:

- (a) receiving written prescriptions;
- (b) taking refill orders;
- (c) entering and retrieving information into and from a database or patient profile;
- (d) preparing labels;
- (e) retrieving medications from inventory;
- (f) counting and pouring into containers;
- (g) placing medications into patient storage containers;
- (h) affixing labels;
- (i) compounding;
- (j) counseling for over-the-counter drugs and dietary supplements under the direction of the supervising pharmacist as referenced in Subsection 58-17b-102(~~55~~53)(~~b~~)(2);
- (k) accepting new prescription drug orders left on voicemail for a pharmacist to review; [and]

(l) performing checks of certain medications prepared for distribution filled or prepared by another technician within a Class B hospital pharmacy, such as medications prepared for distribution to an automated dispensing cabinet, cart fill, crash cart medication tray, or unit dosing from a prepared stock bottle, in accordance with the following operating standards:

(i) technicians authorized by a hospital to check medications shall have at least 1 year of experience working as a pharmacy technician and at least 6 months experience at the hospital where the technician is authorized to check medications;

(ii) technicians shall only check steps in the medication distribution process that do not require the professional judgment of a pharmacist and that are supported by sufficient automation or technology to ensure accuracy (e.g., barcode scanning, drug identification automation, checklists, visual aids);

(iii) hospitals that authorize technicians to check medications shall have a training program and ongoing competency assessment that is documented and retrievable for the duration of each technician's employment and at least 3 years beyond employment, and shall maintain a list of technicians on staff that are allowed to check medications;

(iv) hospitals that authorize technicians to check medications shall have a medication error reporting system in place and shall be able to produce documentation of its use;

(v) a supervising pharmacist shall be immediately available during all times that a pharmacy technician is checking medications;

NABP Model Rules for Sterile Pharmaceuticals

Section 1. Purpose and Scope.

The purpose of this section is to ensure positive patient outcomes through the provision of standards for (1) Pharmacist Care; (2) the preparation, Labeling, and Distribution of Sterile Pharmaceuticals by Pharmacies; and (3) Product Quality and Characteristics. These standards are intended to apply to all Sterile Pharmaceuticals, notwithstanding the location of the patient (eg, home, hospital, nursing home, hospice, doctor’s office). All Compounding Pharmacies and Pharmacists shall practice in accordance with these Rules, the Board’s Good Compounding Practices Applicable to State Licensed Pharmacies, and the current United States Pharmacopeia-National Formulary (USP-NF) chapters on Compounding and sterile pharmaceutical preparations.

Section 2. Definitions.

- (a) “Beyond-Use Date” means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.
- (b) “Bioburden” means the total number of microorganism associated with a specific item prior to sterilization.
- (c) “Biological Safety Cabinet” means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.
- (d) “Critical Areas” means areas designed to maintain sterility of sterile materials.
Sterilized product, container/closures, and equipment may be exposed in critical areas.
- (e) “Critical Surfaces” – Surfaces which may come into contact with or directly impact sterilized product or containers/closures.
- (f) “Cytotoxic” means a pharmaceutical that has the capability of killing living cells.
- (g) “Disinfection” means the process by which surface bioburden is reduced to a safe level or eliminated.
- (h) “Enteral” means within or by way of the gastrointestinal tract or intestine.
- (i) “ISO Class” means the description of an atmospheric environment characterized by the number of particles within a diameter per cubic foot of air.
- (j) “Isolator” means a decontaminated unit, supplied with ISO Class 5 or higher air quality that provides uncompromised, continuous isolation of its interior from the external environment (eg, surrounding cleanroom air and Compounding Pharmacy personnel).
- (k) “Parenteral” means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous or intramuscular routes.
- (l) “Positive Patient Outcomes” include the cure or prevention of disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process so as to improve the patient’s quality of life.
- (m) “Product Quality and Characteristics” include sterility, potency, identity, strength, quality, and purity associated with environmental quality, preparation activities, and checks and tests.
- (n) “Risk Level” of the Sterile Pharmaceutical means the level assigned to a Sterile Pharmaceutical by a Pharmacist that represents the probability that the Sterile Pharmaceutical will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals, or other physical matter.

- (o) “Sterile Pharmaceutical” means any dosage form of a drug, including but not limited to, parenterals (eg, injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

Section 3. Policy and Procedure Manual.

A policy and procedure manual shall be prepared and maintained for the Compounding, Dispensing, Delivery, Administration, storage, and use of Sterile Pharmaceutical Prescription Drugs. The policy and procedure manual shall:

- (a) include a quality assurance program for the purpose of monitoring patient care and Pharmacist Care outcomes, adverse Drug reactions, personnel qualifications, training and performance, product integrity, equipment, facilities, Disinfection, personnel cleansing and gowning, and guidelines regarding patient education;
- (b) be current and available for inspection by a Board of Pharmacy-designated agent;
- (c) include a plan designed to prevent microbiological contamination of sterile Drug products and procedures concerning the validation of any sterilization process;
- (d) include training and other requirements for Pharmacy Compounding personnel involved in aseptic manipulations to ensure adherence to the basic principles of aseptic technique;
- (e) address the management and proper disposal of Cytotoxic and/or infectious waste, if applicable; and
- (f) address how supervisory personnel will monitor the ongoing adherence to procedures and sound practices.

Section 4. Physical Requirements.

- (a) The Pharmacy shall have a designated area with entry restricted to designated personnel for preparing Sterile Pharmaceuticals. This area shall be structurally isolated from other areas with restricted entry or access, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar flow hood and to provide for the proper storage of Drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (b) The Pharmacy preparing Sterile Pharmaceuticals shall have:
 - (1) appropriate environmental control Devices capable of maintaining at least ISO Class 5 conditions in the workplace where Critical Areas and Critical Surfaces are exposed and critical activities are performed and providing for appropriate environment control in accord with USP Chapter 797. Furthermore, these Devices are capable of maintaining ISO Class 5 conditions during all Compounding activities and include laminar airflow hoods and zonal laminar flow of High Efficiency Particulate Air (HEPA) filtered air; use of an Isolator shall also be considered;
 - (2) floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;
 - (3) appropriate disposal containers for used needles, syringes, etc, and, if applicable, for Cytotoxic waste from the preparation of chemotherapy agents and infectious wastes;
 - (4) when Cytotoxic Drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;
 - (5) temperature-controlled delivery container;
 - (6) infusion devices, if appropriate.

- (c) The Pharmacy shall maintain supplies adequate to ensure an environment suitable for the aseptic preparation of Sterile Pharmaceuticals.
- (d) The Pharmacy shall have sufficient current reference materials related to sterile products to meet the needs of Pharmacy staff.

Section 5. Records and Reports.

In addition to standard record and reporting requirements, the following records and reports must be maintained for sterile pharmaceuticals:

- (a) Maintenance schedules, including a system for cleaning and disinfecting the room and equipment;
- (b) Compounding records, as described by Good Compounding Practices Applicable to State Licensed Pharmacies, Appendix B, Subpart I;
- (c) Records demonstrating that adequate disinfection (or Sterilization) was performed for the laminar flow hood and supplies used in the aseptic Compounding operation; and
- (d) Dispensing or Distribution records to document who received the Compounded prescriptions.

Section 6. Delivery Service.

The Pharmacist-in-Charge shall ensure the environmental control and stability of all products shipped. Therefore, any Compounded, Sterile Pharmaceutical must be shipped or Delivered to a patient or patient's agent in appropriate temperature-controlled (as defined by USP Standards) delivery containers and stored appropriately. Information on appropriate storage shall be provided to the patient or patient's agent.

Section 7. Disposal of Cytotoxic and/or Hazardous Wastes.

The Pharmacist-in-Charge is responsible for ensuring that there is a system for the disposal of Cytotoxic and/or infectious waste in a manner so as not to endanger the public health.

Section 8. Emergency Kit.

When Sterile Pharmaceuticals are provided to home care patients, the Dispensing Pharmacy may supply the nurse or patient with emergency Drugs, if the physician has authorized the use of these Drugs by a protocol, in an emergency situation (eg, anaphylactic shock).

Section 9. Cytotoxic Drugs.

In addition to the minimum requirements for a Pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare Cytotoxic Drugs to ensure the protection of the personnel involved.

- (a) All Cytotoxic Drugs should be Compounded in a vertical flow, Class II, Biological Safety Cabinet. Other products should not be Compounded in this cabinet.
- (b) Protective apparel shall be worn by personnel Compounding Cytotoxic Drugs. This shall include disposable masks, gloves, and gowns with tight cuffs.
- (c) Appropriate safety and containment techniques for Compounding Cytotoxic Drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
- (d) Disposal of Cytotoxic waste shall comply with all applicable local, State, and Federal requirements.

- (e) Written procedures for handling both major and minor spills of Cytotoxic agents must be developed and must be included in the policy and procedure manual.
- (f) Prepared doses of Cytotoxic Drugs must be Dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

Section 10. Patient Education and Training.

If appropriate, the Pharmacist must demonstrate or document the patient's training and competency in managing this type of therapy provided by the Pharmacist to the patient in the home environment. A Pharmacist must be involved in the patient training process in any area that relates to Drug Compounding, Labeling, Administration, storage, stability, compatibility, or disposal. If appropriate, the Pharmacist must be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

Section 11. Quality Assurance/Compounding and Preparation of Sterile Pharmaceuticals.

There shall be a documented, ongoing quality assurance control program that monitors personnel performance, component verification and usage, Disinfection, sterilization, equipment, and facilities that are appropriate to the Risk Level of the Sterile Pharmaceutical(s) being prepared. Appropriate samples of finished products shall be examined to ensure that the Pharmacy is capable of consistently preparing Sterile Pharmaceuticals meeting specifications.

- (a) All clean rooms and laminar flow hoods shall be certified by an independent contractor according to the International Organization of Standardization Classification of Particulate Matter in Room Air (ISO14644-1) for operational efficiency at least every six months. Appropriate records shall be maintained.
- (b) There shall be written procedures requiring sampling on a frequent basis and special measures taken when microbial contamination is suspected.
- (c) If bulk Compounding of sterile solutions is performed using chemicals that initially are nonsterile, extensive end-product microbial testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter, pyrogens, and microbes.
- (d) There shall be written justification of the chosen Beyond-Use Dates for Compounded products.
- (e) There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits. Intervals shall be based on the type of operations performed and shall increase as the Risk Level increases.
- (f) There shall be policies and procedures on the retraining or recertification of trained Pharmacy Compounding personnel in various aspects of aseptic behavior. The training program shall include a demonstration of ongoing competency. Training to ensure skills such as aseptic technique, cleanroom behavior, and knowledge of the hazards posed by contaminated drugs shall be conducted.
- (g) Pharmacy Compounding Personnel shall wear sterile garb if conducting one or more aseptic manipulation of sterilized equipment or product.
- (h) An effective Disinfection program shall be implemented, including adequate provisions for preventing emergence of unsafe levels of sporeforming organisms.
- (i) A system shall be in place for monitoring Pharmacy Compounding personnel and environmental conditions.

- (j) A system shall be in place for maintaining any equipment or Devices used to control aseptic conditions.

Section 12. Pharmacist Care Outcomes.

There shall be a documented, ongoing quality assurance control program that monitors patient care and Pharmacist Care outcomes, including but not limited to, the following:

- (a) routine performance of Prospective Drug Utilization Review (DUR) and patient monitoring functions by a Pharmacist, as defined in the Rules of the Board;
- (b) patient monitoring plans that include written outcome measures and systems for routine patient assessment (examples include infection rates, rehospitalization rates, and the incidence of adverse Drug reactions);
- (c) documentation of patient training as specified in Section 10; and
- (d) appropriate collaboration with other health care professionals.

MINNESOTA

MN BReg 6800.3000.

Prescriptions and Distribution of Medication.

Subpart 1. Acceptance of prescription drug orders and distribution of drugs.

A. No licensed pharmacist shall participate in any arrangement or agreement whereby prescription drug orders or filled prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. Provided, however, that nothing in this part prohibits a licensed pharmacist or a licensed pharmacy, by means of its employee or by use of a common carrier, from picking up prescription drug orders or delivering filled prescriptions at the office or home of the prescriber, at the residence of the patient, or at the hospital or long-term care facility in which a patient is confined. A pharmacy may deliver filled prescriptions at the place of employment of the patient or a designated caregiver of the patient only if the pharmacy:

- (1) obtains and documents the authorization of the patient or patient's caregiver for delivery at the place of employment;
- (2) ensures the filled prescription order is delivered directly to the patient or the patient's caregiver as authorized; and
- (3) ensures the security of protected health information.

B. Direct prescription delivery. A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient must, based on the professional judgment of the pharmacist:

- (1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes must include the use of appropriate packaging material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication;
- (2) use shipping containers that are sealed in a manner to detect evidence of opening or tampering;
- (3) develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures must address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug has been compromised during shipment. In these instances, the pharmacy must make provisions for the replacement of the drugs; and
- (4) provide for an electronic, telephonic, or written communication mechanism for a pharmacist, or a pharmacy intern working under the direct supervision of a pharmacist, to offer counseling to the patient. The patient must receive information indicating what the patient should do if the integrity of the packaging or medication has been compromised during shipment.

COLORADO

/COLORADO/COLORADO State Board of Pharmacy Rules and Regulations/CO BReg Title 700. Department of Regulatory Agencies/CO BReg 719. State Board of Pharmacy/CO BReg 719-1. State Board of Pharmacy Rules/CO BReg 20.00.00. Central Prescription Processing/CO BReg 20.00.60. Operational Standards.

**CO BReg 20.00.60.
Operational Standards.**

a. A pharmacy may outsource one or more portions of the dispensing of an order to other pharmacies provided the pharmacies:

1. Have the same owner or have entered into a written central prescription processing contract which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and rules; and

2. Share a common electronic file or have appropriate technology/interface to allow access to information required to process the order; and

3. Are registered with the Board as either prescription drug outlets or non-resident prescription drug outlets, depending on the pharmacy's location. All pharmacies participating in the central prescription processing contract must be located within the United States.

b. The pharmacist manager of the fulfillment pharmacy shall assure that:

1. The pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and

2. The filled prescriptions are shipped in containers, which are sealed in a manner as to show evidence of opening or tampering.

History: Amended Jan. 1, 2013.

NABPLAW 09/2013

COLORADO/COLORADO State Board of Pharmacy Rules and Regulations/CO BReg Title 700. Department of Regulatory Agencies/CO BReg 719. State Board of Pharmacy/CO BReg 719-1. State Board of Pharmacy Rules/CO BReg 3.01.00 Packaging/CO BReg 3.01.34.

CO BReg 3.01.34

a. Each packaged container shall be labeled according to Rule 3.01.20(a) through (i).

GEORGIA

(i) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which reasonably determines whether the medications distributed by the mails or other common carriers have been received by the enrollee and through which a pharmacist employed by the group model health maintenance organization or a pharmacy intern under his or her direct supervision is enabled to offer counseling to the enrollee as authorized by and in accordance with his or her obligations under Code Section 26-4-85, unless the enrollee refuses such consultation or counseling pursuant to subsection (e) of such Code section. In addition, the enrollee shall receive information indicating what he or she should do if the integrity of the packaging or medication has been compromised during shipment;

(ii) In accordance with clinical and professional standards, the State Board of Pharmacy shall promulgate a list of medications which may not be delivered by the mails or other common carriers. However, until such list is promulgated, the group model health maintenance organization shall not deliver by use of the mails or other common carriers Class II controlled substance medications, medications which require refrigeration, chemotherapy medications deemed by the federal Environmental Protection Agency as dangerous, medications in suppository form, and other medications which, in the professional opinion of the dispensing pharmacist, may be clinically compromised by distribution through the mail or other common carriers;

(iii) The pharmacy shall utilize, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other standards adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these; and

(iv) The pharmacy shall establish and notify the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs.

For purposes of this subparagraph, the term "group model health maintenance organization" means a health maintenance organization that has an exclusive contract with a medical group practice to provide or arrange for the provision of substantially all physician services to enrollees in health benefits plans of the health maintenance organization; or

(C) A pharmacist or pharmacy to dispense a prescription and deliver it to another pharmacist or pharmacy to make available for a patient to receive the prescription and patient counseling according to Code Section 26-4-85. The State Board of Pharmacy shall adopt any rules and regulations necessary to implement this subparagraph;

(12) Unless otherwise authorized by law, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the prior authorization of the practitioner ordering or prescribing the same;

ILLINOIS

H) Beyond use date and time;

I) Identity of pharmacist compounding and dispensing, or other authorized individual; and

J) Auxiliary labels storage requirements, if applicable.

3) The pharmacist-in-charge shall ensure that records are maintained for 5 years and are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information:

A) Patient profile;

B) Medication record system;

C) Purchase records; and

D) Lot numbers of the components used in compounding sterile prescriptions/orders traceable to a specific patient, if not included on patient profile and if the preparation is not utilized within 48 hours after preparation.

f) Delivery Service. The pharmacist-in-charge shall assure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded, sterile pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers.

g) Cytotoxic Drugs. The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs:

1) Safety and containment techniques or devices for compounding cytotoxic drugs shall be used.

2) Disposal of cytotoxic waste shall comply with all applicable local, State and federal requirements.

3) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

4) The pharmacy must have as a reference Safe Handling of Hazardous Drugs Video Training Program and Workbook (American Society of Health-System Pharmacists (ASHP), 7272 Wisconsin Avenue, Bethesda MD 20814, (301)657-3000, <http://www.ashp.org>).

h) Emergency Medications. Pharmacies that dispense compounded sterile preparations to patients in facilities off site or in the patient's residence shall stock supplies and medications appropriate for treatment of allergic or other common adverse effects, to be dispensed upon the prescription or order of an authorized prescriber.

LOUISIANA

b. appropriate environmental control devices capable of maintaining at least Class 100 environment in the workplace where critical objects are exposed and critical operations are performed. These devices, e.g., laminar air flow hoods, and other zonal laminar flow hoods utilizing High Efficiency Particulate Air (HEPA) filters, shall be capable of maintaining Class 100 conditions during normal activity;

c. appropriate refrigeration for storing supplies and sterile products requiring refrigeration subsequent to their preparation and prior to their dispensing or administration to patients. The pharmacy shall maintain documentation of refrigeration integrity, in accordance with its policies and procedures;

d. appropriate disposal containers for used needles, syringes, and other sharps, and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes; and

e. temperature-controlled delivery containers, when required.

3. The pharmacy shall maintain supplies adequate to ensure an environment suitable for the aseptic preparation of sterile products. Within the sterile compounding area, prescription drugs, devices, and related materials shall not be stored in shipping containers constructed of corrugated cardboard or other high particulate-producing materials.

4. The pharmacy shall maintain current reference materials related to sterile products accessible to all personnel.

D. Drug Handling. Any sterile compounded product shall be shipped or delivered to a patient in appropriate temperature-controlled delivery containers as defined by USP standards and appropriately stored.

E. Cytotoxic Drugs. In addition to the minimum standards for a pharmacy established by the board, the following requirements are established for pharmacies that prepare cytotoxic drugs, to insure the protection of the personnel involved.

1. All cytotoxic drugs shall be compounded in a vertical flow, Class II Biological Safety Cabinet. Other products shall not be compounded in this cabinet.

2. Personnel compounding cytotoxic drugs shall wear protective apparel, including disposable masks, gloves, and gowns with tight cuffs.

3. Personnel compounding cytotoxic drugs shall use appropriate safety and containment techniques.

Naloxone distribution

502 Utahns died last year of drug overdoses

323 of them from prescription drug overdoses

261(52%) of them from prescription opioids

75% are not suicides

93% died at a residence (very likely someone else was around)

Naloxone can reverse opioid overdoses

Naloxone is a non-controlled prescription medication

It is just not available or thought of outside of the EMS/ER system

It is available in more than a dozen states, hundreds of communities

>10,000 documented rescues

Utah actions to reduce deaths:

Prescription pain medication program (uptic in deaths after funding eliminated)

Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain (2009)

Dose triggering “think more about what you are prescribing for patients” = “120-200mg MED seems reasonable”

The Washington State guideline (WSAMDG, 2007) suggested a threshold of 120 mg of morphine equivalent per day, but has been criticized for that decision. It seems reasonable to increase clinical vigilance at daily doses that exceed 120-200 mg of morphine equivalent per day. In one recent study, 92% of patients on opioid doses at or above 200 mg morphine equivalents had developed ataxic or irregular breathing (Walker, 2007). 120mg limit is mentioned in several other sections of the guideline, but not emphasized in practice!

Washington state mandatory trigger is 120mg MED. Paper in 2012 showed dramatic reduction in deaths in 2010

Prescriber exam on safe prescribing practices – implemented this year

Carol Spackman Moss is introducing 2 bills

HB 11 – Overdose reporting amendments – “911 bill”

?? – Overdose Emergency Treatment – “authorizing administration of naloxone bill” – the intent as discussed with Rep Moss, USAAV committee, poison center, many other experts is to model states that have through simple language and minimal legislative impact authorized anyone to administer. Some have felt need for writing in “3rd party administration” amendments, others have not.

Challenges: central source for gathering material for kits, uniform education of patients, families, friends doctors, pharmacists, payment (Medicaid \$, insurance), points of distribution.....

Utah Guidelines:

Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:
(AND GIVE NALOXONE IF AVAILABLE)

Signs of respiratory depression:

- Snoring heavily and cannot be awakened
- Periods of ataxic (irregular) or other sleep disordered breathing
- Having trouble breathing
- Exhibiting extreme drowsiness and slow breathing
- Having slow, shallow breathing with little chest movement
- Having an increased or decreased heartbeat
- Feeling faint, very dizzy, confused or has heart palpitations

NALOXONE RESCUE PROJECT MEETING

November 25, 2013

Need for action

Action needed

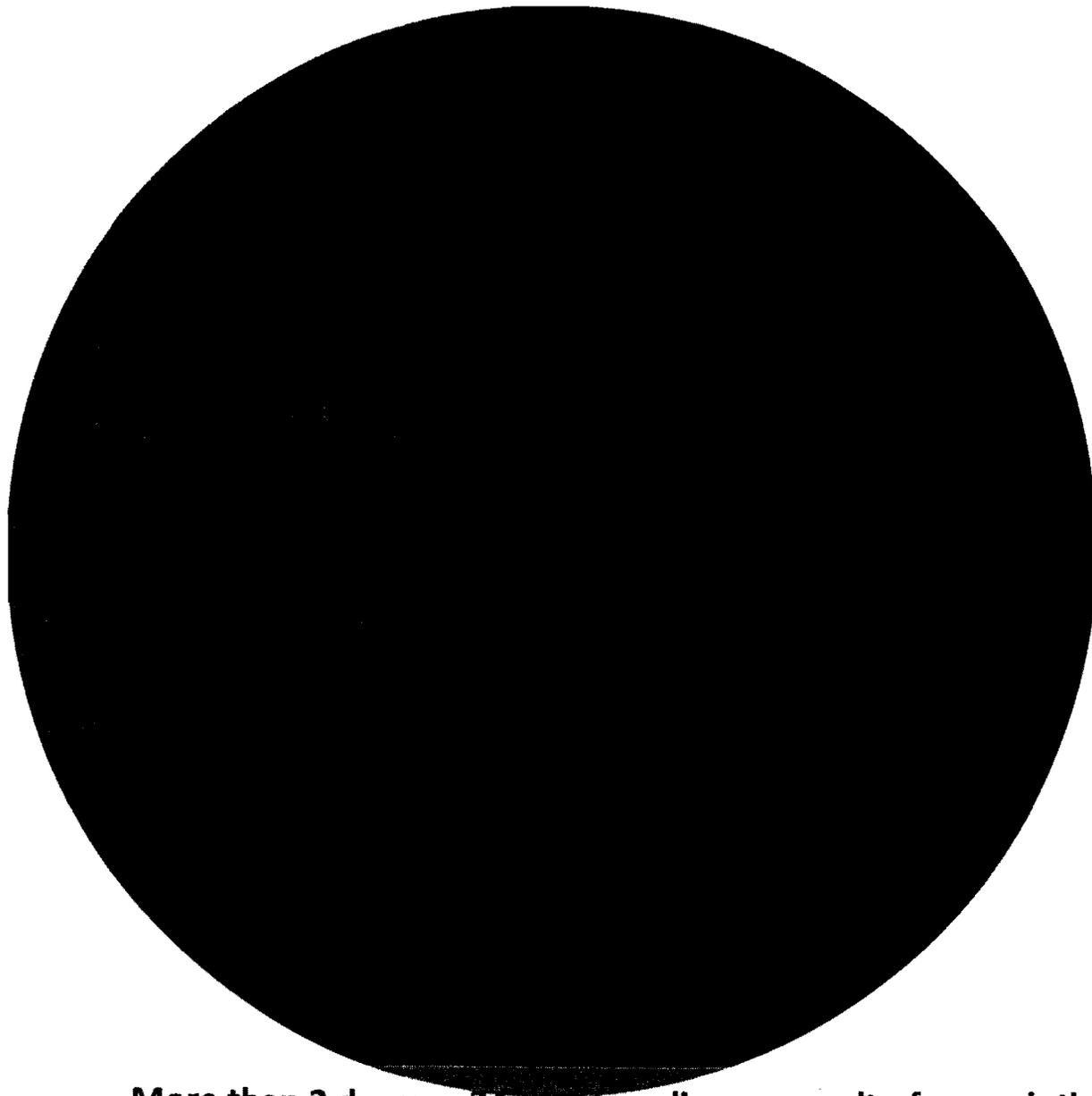
How to accomplish
needed action

Rule-making and/or
Legislation

**White House, CDC, and UTAH's ME deem
overdose deaths
"EPIDEMIC"**

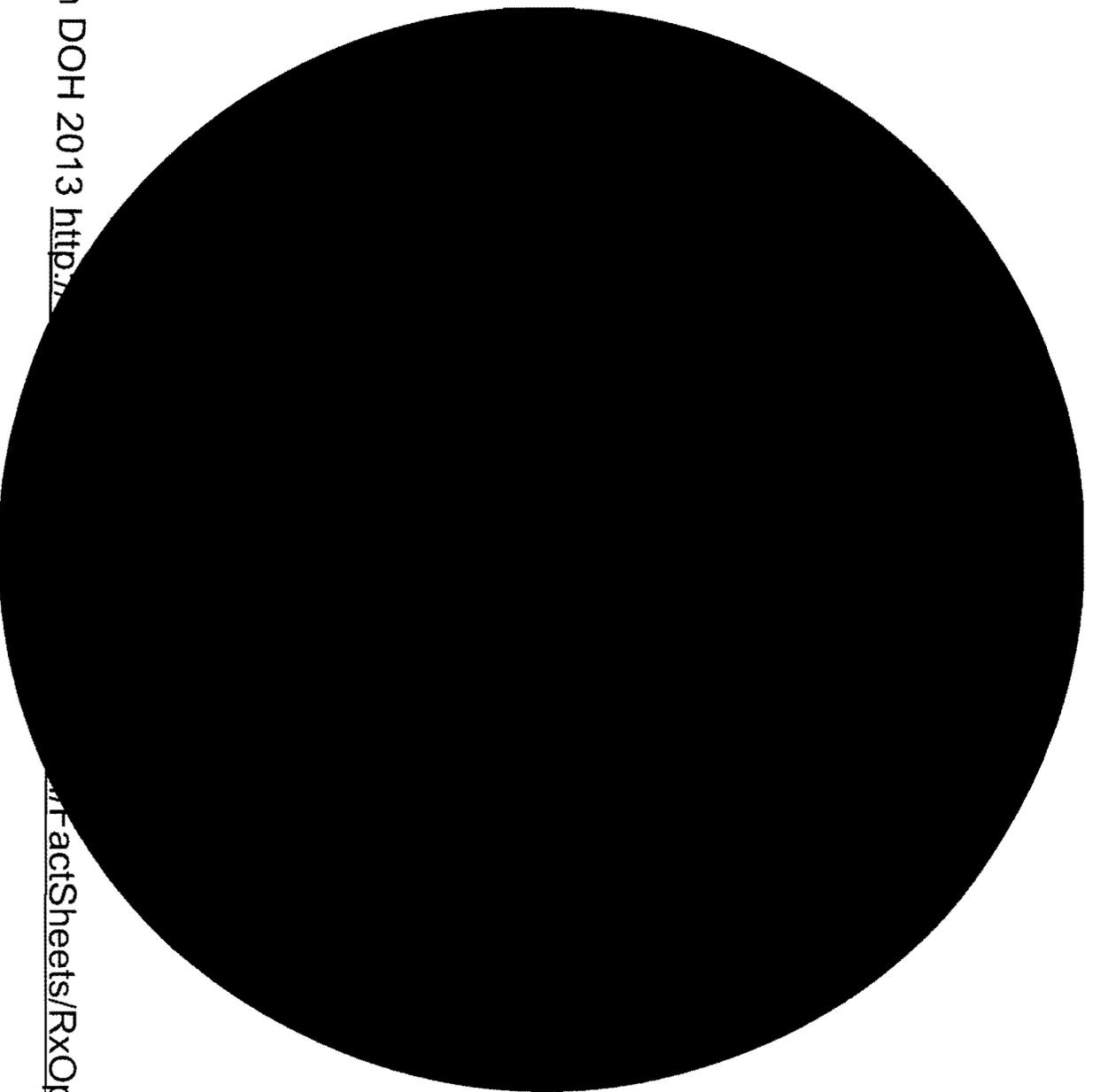
**• OUR FATHERS, MOTHERS,
SPOUSES, and CHILDREN are dying
from this epidemic!**

**• The majority of these people are
NOT addicts!**



- Prescription Opioid
- Prescription Other
- Heroin/Cocaine
- Other illicit

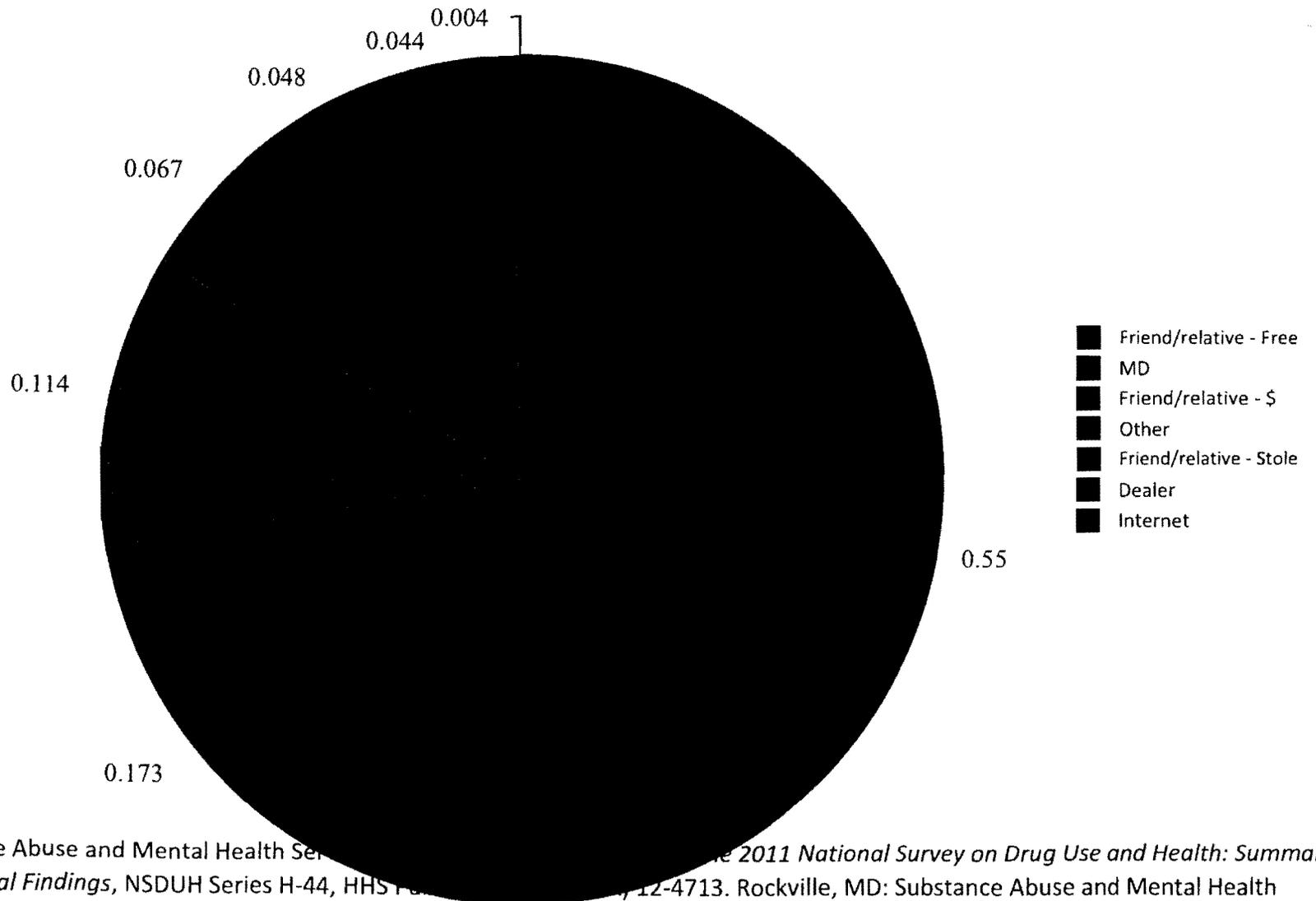
More than 2 dozen – 24 - Utahns die as a result of prescription opioids each month!
Utah DOH 2013 <http://www.health.utah.gov/vipp/pdf/FactSheets/RxOpioidDeaths.pdf>



■ Opioids
■ Other

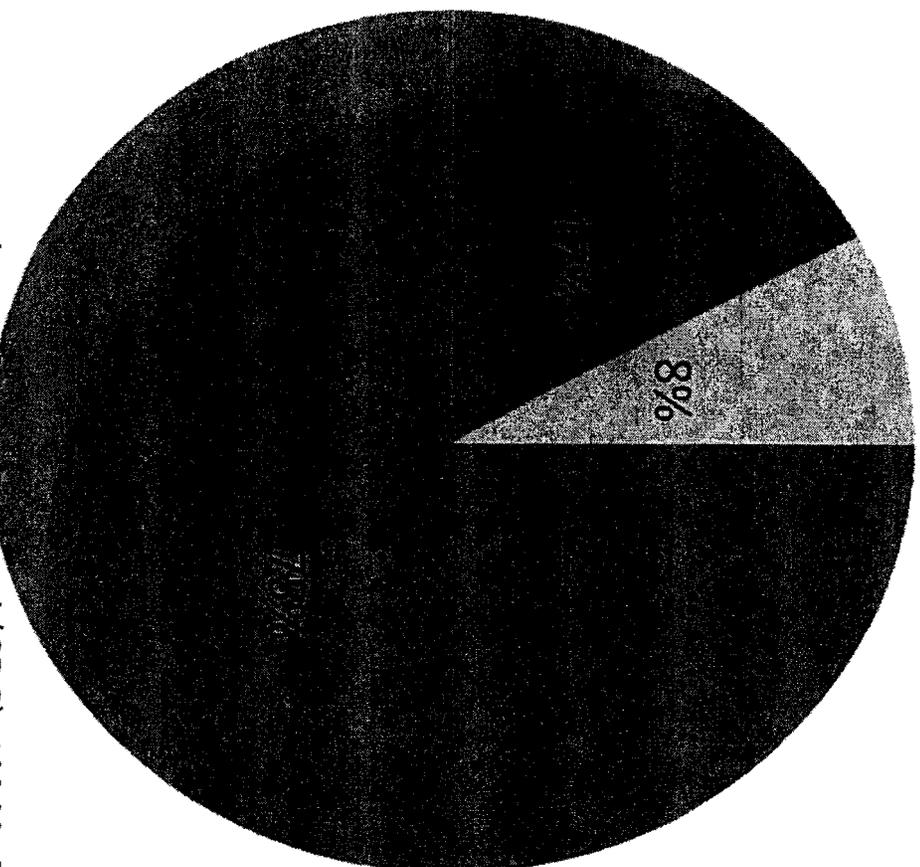
Utah DOH 2013 <http://www.utah.gov/factsheets/RxOpioidDeaths.pdf>

Sources of drugs:



Substance Abuse and Mental Health Services Administration. (2012). *2011 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-44, HHS Publication (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.

MOST DIDN'T MEAN TO DO IT "OOPS"!

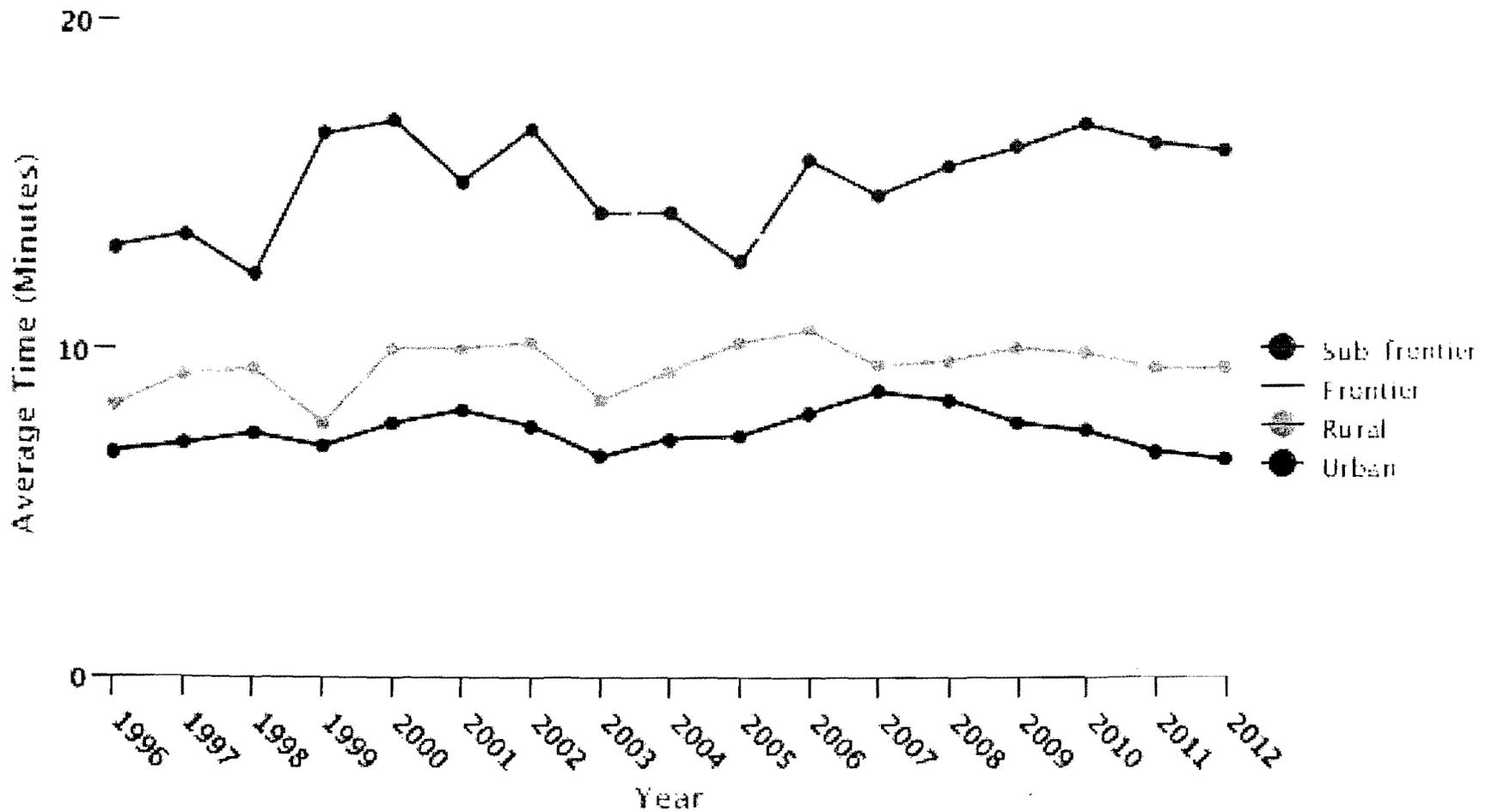


- Unintentional
- Suicide
- Undetermined

Jones, Mack, Paulozzi (CDC). JAMA, February 20, 2013

Utah DOH 2013 <http://www.health.utah.gov/vipp/pdf/FactSheets/RxOpioidDeaths.pdf>

Time (Avg. Minutes) From Dispatch of EMS to Arrival at Scene by County Type, Utah, 1996-2012

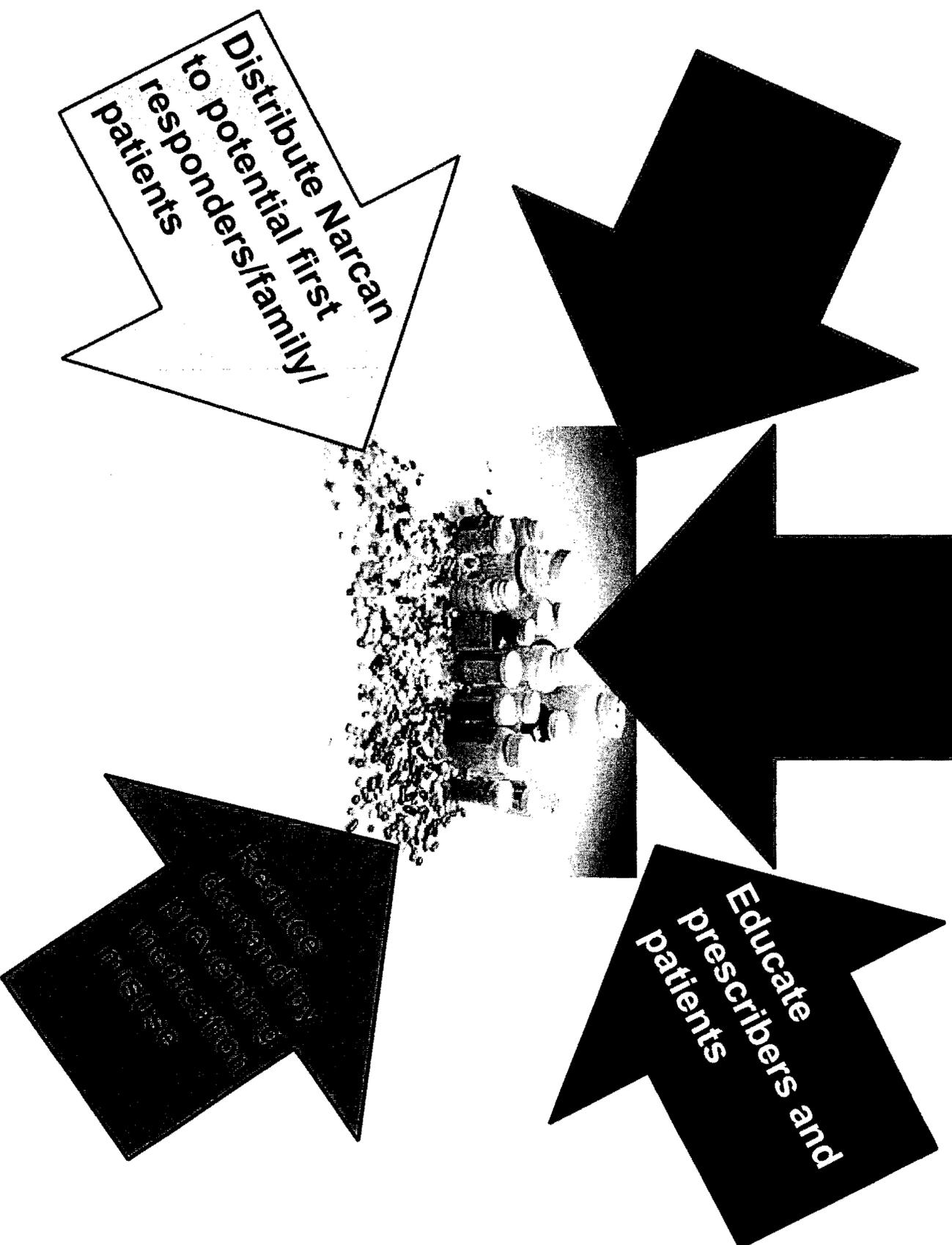


Data Source Utah Bureau of Emergency Medical Services, Utah Department of Health

Who should receive naloxone rescue kit?

- Received emergency medical care involving opioid intoxication or poisoning
- Suspected history of substance abuse or nonmedical opioid use
- Prescribed methadone or buprenorphine
- Higher-dose (>50 -100mg morphine equivalent/day) opioid prescription
- Receiving any opioid prescription for pain plus:
 - Rotated from one opioid to another because of possible incomplete cross tolerance
 - Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection, or other respiratory illness or potential obstruction.
 - Renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS
 - Known or suspected concurrent alcohol use
 - Concurrent benzodiazepine or other sedative prescription
 - Concurrent antidepressant prescription
- Patients who may have difficulty accessing emergency medical services (distance, remoteness)
- Voluntary request from patient or caregiver

Opportunities to eliminate overdose deaths



Why DISTRIBUTE Naloxone?

- **Even after calling 911, help might not arrive in time to save the individual who has overdosed.**
- **Naloxone is an antagonist/blocking medication that can quickly reverse overdose from opioids (i.e. heroin, oxycodone, methadone) and prevent death.**
- **Naloxone is:**
 - **very safe**
 - **not a controlled substance**
 - **approved by the FDA to reverse opioid overdoses**

Endorsements for expanded access to Naloxone

- Drug Policy Alliance
- ONDCP
- Finally, American Medical Association – including recent legislative support in Colo and NJ
- American Society of Addiction Medicine (see next slides)
- SAMHSA – released “Tool-kits” re: naloxone (see next slides)
- FDA/NIDA – “endorsement” (see next slides)
- Utah professionals – (see next slides)

On ASAM website: example of expanded access:
University of Pennsylvania pain treatment MD

- **How patients respond:** In general, patients respond relatively well to being asked to sign the agreement...The agreement is part of a longer conversation about the use of opioids and their potential misuse, as well as our concern about accidental overdose. All of our patients also are trained on how to use nasal Naloxone.

S A M H S A Opioid Overdose TOOLKIT: (2013)

Emergency medical personnel, health care professionals, and patients increasingly are being trained in the use of the opioid antagonist naloxone (Narcan), which is the treatment of choice to reverse the potentially fatal respiratory depression caused by opioid overdose.

Prescribers:

CONSIDER PRESCRIBING NALOXONE ALONG WITH THE PATIENT'S INITIAL OPIOID PRESCRIPTION.

Family/Caregivers:

Learn the signs of overdose and how to use naloxone to keep it from becoming fatal

EMS:Naloxone (Narcan) should be administered to any person who shows signs of opioid overdose, or when overdose is suspected

Community:**Ensure ready access to naloxone.**

FDA/NIDA “endorsement”

- Studies of the use of takehome naloxone for persons receiving high dosages of prescription opioids and of those abusing the drugs are warranted to determine whether such interventions reduce mortality and morbidity. In particular, studying the effectiveness of layperson-administered naloxone in reversing overdose from long-acting and extended-release opioids is essential.

- Compton, Volkow, Throckmorton, Lurie 2013 (FDA and NIDA)

Utah Professionals' Endorsements

- Dr. Thomas Martin, medical director Poison Control Center
- Dr. Erik Barton, ER medical director and IN naloxone researcher
- Drs. Lynn Webster and Michael Jaffe, American Association of Pain Medicine
- Dr. David Young, Chair of the Board of Pharmacy
- Dr. Elizabeth Howell, Chair of the Utah Board of Medicine

– See summary of their statements in attachment

502 Utah overdoses

Chris Stock's thoughts about naloxone access

- 179 - heroin or other non-prescribed
- When to get naloxone?
 - Seeking services at HRP
 - Released from prison
 - Completed sub abuse treat
 - Completed Detox
 - Release from ER OD visit
- Where to get naloxone?
 - HRP via collaborative practice agreement
 - VOA via collaborative practice agreement
 - ERs via prescription
 - Pharmacies via collaborative practice agreement
 - Health Department
- 323 prescribed opioids
- When to get naloxone?
 - At MD visit
 - At pharmacy visit
 - Other?
- Where to get naloxone?
 - Pharmacy
 - By prescription along with opioid rx
 - Via collaborative practice agreement
 - HRP by referral if pharmacy not available
 - Health Department

Where will the naloxone rescue kit come from?

Naloxone requires a prescriber

- Any pharmacy?
- Any pharmacy wholesaler?
- Selected pharmacies? Trained/certified?
 - By whom?
- Will a supplier of already made-up kits step up?
 - Health department
 - HRP
 - Other?

Naloxone dosage forms

- **Intranasal – 1mg/1ml concentration**
 - **No needles**
 - **No diversion for other uses**
 - **No worry about needle sticks and injuries and needle phobia**
 - **Gentler awakening?**
 - **Supported by Dr. Barton, U of U and numerous others**
- **Intramuscular – 0.4mg/ml or 1mg/ml conc.**
 - **Retractable needle syringes available, ? cost**

Intra-nasal naloxone kit

2 luerlock naloxone 2mg/2ml syringes

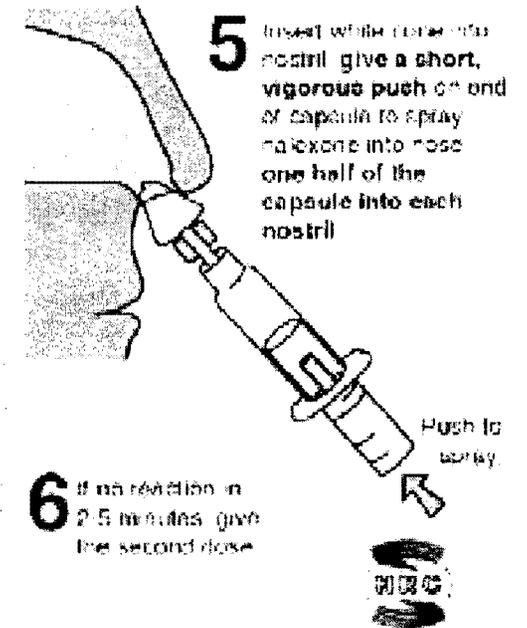
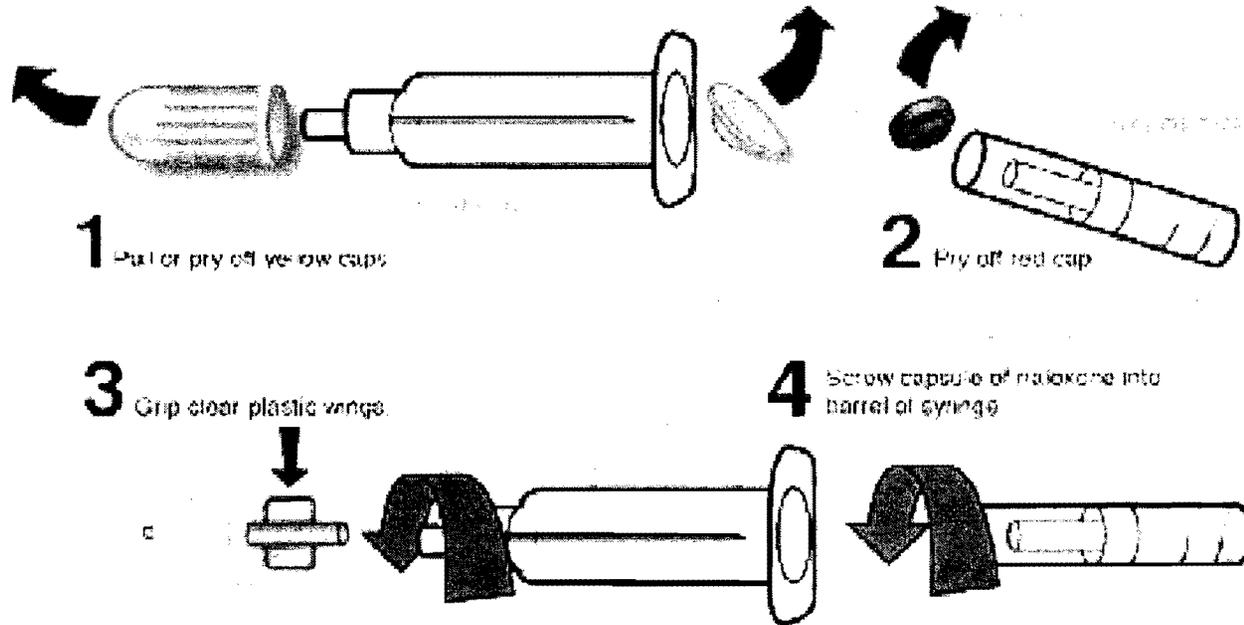
2 nasal luerlock adapters

Instructions

pouch/container

\$25-50 per kit

HOW TO GIVE INTRANASAL NALOXONE



Intra-nasal naloxone kit

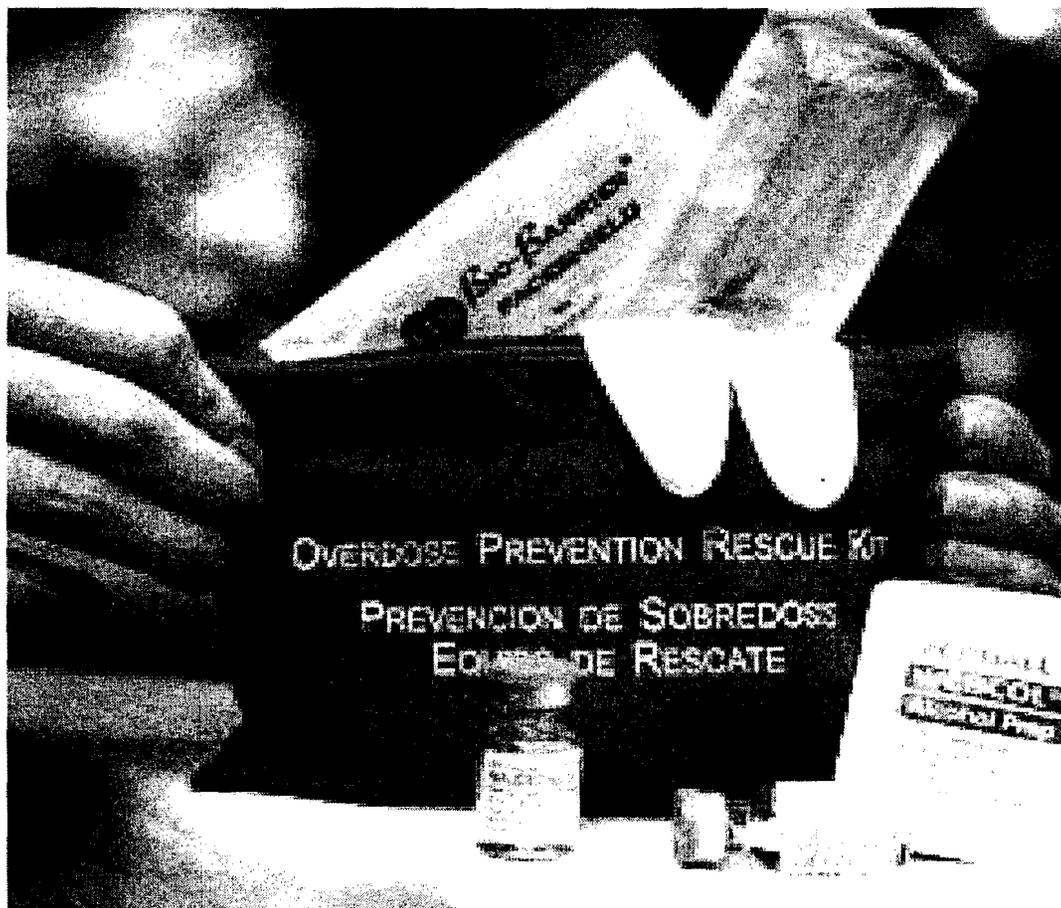
2 naloxone 0.4mg/ml x 1ml vials

2x3ml syringes (retractable?)

Instructions

pouch/container

\$15-45 per kit?



**What do we do next to prevent any
more deaths?**

Legalities?

- Currently – naloxone is fully available, legally prescribable, not controlled or restricted
- Uncertainties – “prescribing” or dispensing to a “third party”. “Possession of naloxone prescribed to others is technically not authorized. However, in practice many prescription drugs are commonly held by caregivers. If you are a provider of both the caregiver and the person at risk of overdose, the prescription should be written for the person potentially at risk for overdose.”

Prescribetoprevent.org

- What have other states done? See next slide for examples and attachments from other states’ boards of pharmacy