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May 19, 2014

David C. Young, Pharm. D.
Chair, Utah Board of Pharmacy
160 East 300 South
Salt Lake City, Utah 84111

RE: Implementation Schedule for ASHP Accreditation

Dear Dr. Young,

The Utah College of Applied Technology (UCAT) supports the Utah Board of Pharmacy in its decision to require accreditation of all pharmacy technician programs by the American Society of Health-System Pharmacists (ASHP), and respectfully requests that the Board adopt the schedule provided by the Pharmacy Technician Certification Board (PTCB) for full ASHP implementation by the year 2020.

The PTCB administers the Pharmacy Technician Certification Exam (PTCE), the only pharmacy technician certification exam recognized in all 50 states. Many employers will only hire technicians who hold PTCE certification. The PTCB board of governors includes representatives from the ASHP, American Pharmacists Association and the National Association of Boards of Pharmacy. The PTCB has recently determined that beginning in 2020 it will require each new candidate to have completed an ASHP-accredited pharmacy education program to qualify for certification.

The pharmacy technician-specific ASHP accreditation requires that approved training programs first hold institutional accreditation. Local governance and institutional accreditation require approval of new programs and changes to existing programs. The PTCB implementation schedule provides time for programs to satisfy these approval requirements for adjustments that may be needed under ASHP accreditation, such as changes in curriculum, facilities, or affiliation agreements with dispensing and retail pharmacies. It ensures that the current board-approved programs can teach out existing students and provide continued access to pharmacy technician training and a supply of highly-qualified technicians to local pharmacies without disruption during the transitional period.

Six of UCAT's eight applied technology college (ATC) campuses currently have Board-approved pharmacy technician training programs as part of UCAT's statewide mission to meet the needs of Utah employers. Each campus carries institutional accreditation by the Council on Occupational Education (COE), which requires ongoing employer direction and monitors each pharmacy technician program on an annual basis for defined thresholds in completion, job placement and licensure. This oversight ensures ongoing protection to the public and high quality instruction while programs complete the ASHP programmatic accreditation process.

Sincerely,

Rob Brems, President
Utah College of Applied Technology

Tom Bingham, Chair
UCAT Board of Trustees

c: Evan J. Vickers, Senator
Richard J. Oborn, Bureau Manager, Division of Occupational and Professional Licensing

R156-17b-303a. Qualifications for Licensure - Education Requirements.

(1) In accordance with Subsections 58-17b-303(2) and 58-17b-304(7)(b), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy Foundation.

(2) In accordance with Subsection 58-17b-304(7), an applicant for a pharmacy intern license shall demonstrate that he meets one of the following education criteria:

(a) current admission in a College of Pharmacy accredited by the ACPE by written verification from the Dean of the College;

(b) a graduate degree from a school or college of pharmacy which is accredited by the ACPE; or

(c) a graduate degree from a foreign pharmacy school as established by a certificate of equivalency from an approved credentialing agency defined in Subsection (1).

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician shall complete a training program that is:

~~(a) accredited [or conducted by the American Society of Health System Pharmacists] by ASHP[;]; or~~

(b) conducted by:

(i) the National Pharmacy Technician Association[;];

(ii) Pharmacy Technicians University; or

(iii) a branch of the Armed Forces of the United States, and

(c) meets the following standards:

~~(a)~~ (i) completion of at least 180 hours of directly supervised practical training in a licensed pharmacy as determined appropriate by a licensed pharmacist in good standing; and

~~(b)~~ (ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technicians in training that address:

~~(i)~~ A the specific manner in which supervision will be completed; and

~~(ii)~~ B an evaluative procedure to verify the accuracy and completeness of all acts, tasks and functions performed by the pharmacy technician in training.

(4) An individual shall complete a pharmacy technician training program and successfully pass the required examinations as listed in Subsection R156-17b-303c(4) within two years from the date of the first day of the training program, unless otherwise approved by the Division in collaboration with the Board.

(a) An individual who fails to apply for and obtain a pharmacy technician license within the two-year time frame or within six months after completion of a

pharmacy technician training program, whichever comes first:

- (i) is no longer eligible for employment as a technician-in-training and shall work in the pharmacy only as supportive personnel; and
- (ii) shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

(5) (a) Pharmacy technician training programs that received Division approval on or before April 30, 2014 are exempt from satisfying standards established in Subsection R156-17b-303a(3) for students enrolled [until January 4] on or before December 31, 2016. [The Division will accept and review applications for approval of pharmacy technician training programs submitted on or before March 31, 2014. The criteria used by the Division to determine whether a pharmacy technician program is approved shall be the criteria established in Subsection R156-17b-303a(2) of the rule effective immediately prior to this rule.]

(b) A student in a program exempt under Subsection (5)(a) shall comply with the program completion deadline and testing requirements in Subsection (4), except that their license application shall be submitted to the Division no later than December 31, 2019.

(c) A program in ASHP candidate status is required to notify a student prior to enrollment that if the program is denied accreditation status while the student is enrolled in the program, the student will be required to complete their education in another program with no assurance of how many credits will transfer to the new program.

(d) A program in ASHP candidate status that is denied accreditation shall immediately notify the Division, enrolled students, and student practice sites, of the denial. The notice shall instruct each student and practice site that:

(i) the program no longer satisfies the pharmacy technician license education requirement in the State of Utah; and

(ii) enrollment in a different program meeting requirements established in Subsection R156-17b-303a(3) is necessary for the student to complete their training and to satisfy the pharmacy technician license education requirement in the State of Utah.

(6) An applicant for licensure as a pharmacy technician is deemed to have met the qualifications for licensure in Subsection 58-17b-305(1)(f) and 58-17b-305(1)(g) if the applicant:

(a) is currently licensed and in good standing in another state and has not had any adverse action taken on that license;

(b) has engaged in the practice as a pharmacy technician for a minimum of 1,000 hours in that state within the past two years or equivalent experience as approved by the Division in collaboration with the Board; and

(c) has passed and maintained current PTCB or ExCPT certification[; and

(d) has passed the Utah Pharmacy Technician Law and Rule Examination].

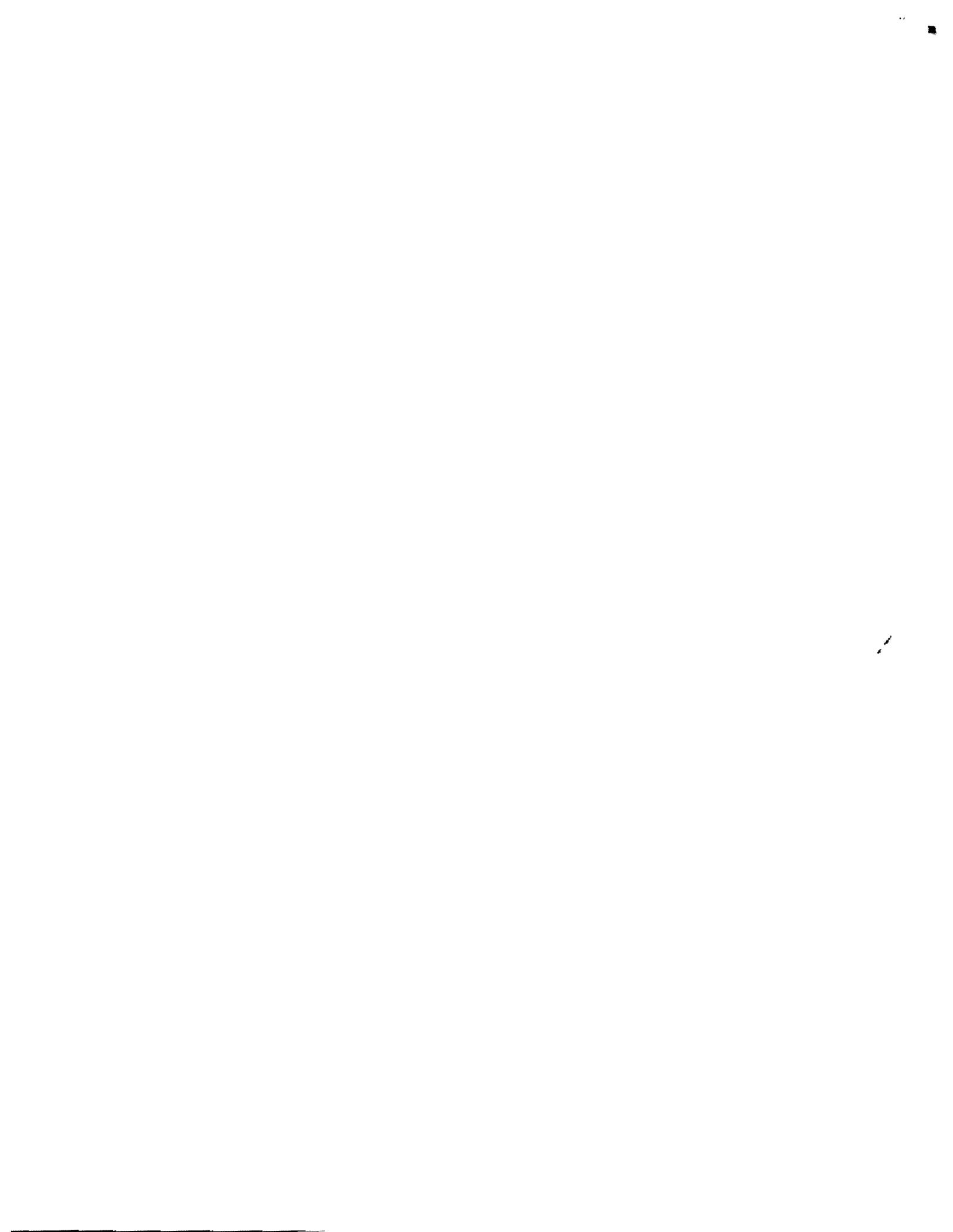
R156-17b-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 17b, as used in Title 58, Chapters 1 and 17b or this rule:

(1) "Accredited by ASHP " means a program that:

(a) was accredited by the ASHP on the day on which the applicant for licensure completed the program; or

(b) was in ASHP candidate status on the day on which the applicant for licensure completed the program.



	2013	2014	Apr-14
Administrative Filings	37	14	2
Criminal Filing/Felony	3	0	0
Letter of Concern	60	58	3
PR/Outreach	3		
Cases Received	710	167	51
Case Assigned	676	163	49
Closed Cases	731	179	71
Citations Issued	103	7	0
Pharmacy Inspections	225	69	33
Pharmacy Alerts	191	60	19
Dr. Shopper/Law Enforcement Letters	209	103	41

NOTES: Pharmacy Group

Apr-14

New Positions

The Division has posted 2 new positions. One is for a Pharmacy Investigator, and the other is for a Pharmacy Inspector.

Pharmacy Training

On Saturday, May 17, 2014, the Pharmacy Group attended training for the Pharmacy Law Review Training at the University of Utah. They went over Federal Laws and Rules relating to compounding, and State Laws and Rules regulating Pharmacy.

Administrative Action

The Division took action against a Pharmacy Technician for Drug Diversion. The licensee Surrendered her license.

Administrative Action

The Division took action against Firestone Pharmacy and Value Med Rx Pharmacy for Pharmacy violations. Both companies signed a Stipulation and Order. They have closed their doors and are no longer practicing.

Citation

Citation was issued to an unlicensed person for practicing Pharmacy and medicine without being licensed to do so.

Compounded Mouthwash Guidelines

Compounded mouthwashes are used to treat mouth sores. These preparations are classified as "moderate compounds" by Utah State Board of Pharmacy. With this classification, certain documentation, equipment and training requirements must be observed when compounding these medications. Pharmacies wish to make compounded mouthwashes containing Antacid, Diphenhydramine, and Viscous Lidocaine (1:1:1) liquid ingredients are able to do so if abiding by the following guidelines. This applies to all pharmacy license categories.

Standard Operating Procedures:

The pharmacy must have a Standard Operating Procedure (SOP) on the premises to show how the compound will be made. This needs to include equipment used, and the procedure for making the compound.

Equipment:

In order to accurately measure the ingredients of a Magic Mouthwash, graduated cylinders of appropriate size must be available in the pharmacy.

Good Compounding Practice:

Make sure the work area is clean and orderly, including any measuring devices. Good personal hygiene should be followed and water should be distilled or purified.

Master Formulation Record:

Each compound is required to have a Master Formulation Record (MFR). It must contain the following information.

- Name, strength, dosage form of the preparation
- Calculations required to determine and verify quantities of components and doses of active pharmaceutical ingredients.
- Description of ingredients and their quantities.
- Compatibility and stability information, including references if appropriate.
- Equipment required to prepare preparation.
- Detailed mixing instructions.
- Sample labeling information including: generic name and quantity or concentration of each active ingredient, assigned Beyond Use

Date (BUD), storage conditions, and prescription or control number.

- Packaging and storage requirements
- Description of final preparation.
- Quality control measures and expected results.

The MFR is a permanent record kept at the pharmacy. It is the reference used to make this version of the compound each time. If the compound is altered from the MFR, then a new MFR needs to be created for the variation.

Compounding Record (CR):

This is the record for each, individual compound made. It shall contain the following information:

- The name, strength and dosage form of the preparation.
- MFR reference for the preparation
- Names and quantities of all components.
- Source, lot numbers and expiration dates of components.
- Total quantity compounded.
- Name of person(s) who prepared the preparation, who performed the quality control procedures, and who approved the preparation.
- Date of preparation.
- Assigned control or RX number
- Assigned BUD
- Duplicate label as described in the MFR
- Description of final preparation
- Results of quality control procedures
- Documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver.

The CR can be kept either in a designated location, such as a binder, or attached to the hard copy of the prescription. It must be kept for as long as a hard copy is retained.

Pharmacies can make up a blank CR to fill in each time a Magic Mouthwash is made.

Naming the Compound:

Although the term "Magic Mouthwash" is commonly used, the prescription needs to be named with its active ingredients. For example

Lidocaine:diphenhydramine:antacid 1:1:1 mouthwash. Abbreviations are acceptable as long as the abbreviation lends itself to only one drug.

Labeling:

All compounds need to have on their label a statement that says "This is a compounded preparation". Also, any appropriate auxiliary labels need to be attached. For example: shake well, refrigerate.

Beyond Use Date:

The BUD is 30 days at room temperature for oral mucosal preparations, and 14 days refrigerated for oral preparations (swallowed). Make sure the BUD is on the prescription label.

Storage and Handling of Rx:

Make sure any appropriate storage and handling instructions are included with the prescription.

Training Documentation:

Documentation of training is required for all personnel who will be involved in the making of the compound. Training should include familiarity with the SOP, calibration of scale (if appropriate), how the compound is made, and how the compound is documented. Training shall be completed annually.

If a pharmacy is making compounded mouthwashes and following the above guidelines, they would be considered in compliance with the Board of Pharmacy's requirements.

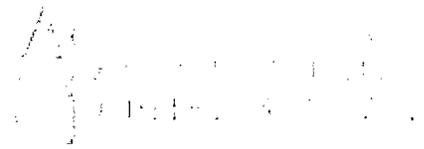
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R156-17b-102. Definitions.

(39) "Prepackaged" or "Prepackaging" means the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment in which the prepackaging occurred.



#6



Published on *American Society of Consultant Pharmacists* (<https://www.ascp.com>)

[Home](#) > Repackaging of Medications from Other Pharmacies

Repackaging of Medications from Other Pharmacies

Nursing facilities have sometimes requested their LTC pharmacy to repackage medications obtained from a community or mail-order pharmacy in conventional bottle and vial packaging. The facility hopes to obtain the special packaging they need while allowing the resident to obtain medications through their pharmacy benefit plan. Although the goal is understandable, this strategy is not necessarily a suitable answer to the problem.

In 1998, the American Society of Consultant Pharmacists asked legal counsel to provide an opinion on the legality of a pharmacy repackaging medications dispensed by another pharmacy. In summary, the following problems are presented when a pharmacy is asked to repackage medications from another pharmacy:

- This practice may be inappropriate under the Food and Drug Administration's Compliance Policy Guide (CPG 7132b.10), especially since community pharmacies rarely provide lot numbers and manufacturer expiration dates on labels of their dispensed prescriptions
- The pharmacy that repackages increases its risk of liability because it assumes responsibility for the medications dispensed by the original pharmacy
- This practice may also violate state laws

For these reasons, pharmacies are generally advised not to repackage medications dispensed by another pharmacy unless certain provisions are in place to protect the integrity of the product and communicate lot and expiration information. However, some state mandate that long-term care pharmacies repackage medications under certain circumstances.

Examples of states that allow/mandate repackaging (not an exhaustive list):

- [Alabama](#) ^[1] (see Question #6)
- [California](#) ^[2] (PDF)
- [Florida](#) ^[3]
- [Minnesota](#): "[Long Term Care Resident Access to Pharmaceuticals Act](#)" ^[4]
- [Pennsylvania](#): "[Long-Term Care Patient Access to Pharmaceuticals Act](#)" ^[5]

Examples of states that do not allow repackaging (not an exhaustive list):

- [North Carolina](#) ^[6] (see item 2046, PDF)



R156-17b-102. Definitions.

(39) "Prepackaged" or "Prepackaging" means the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment in which the prepackaging occurred.



58-17b-302. License classifications of pharmacy facilities.

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

R156-17b-615. Operating Standards - Class C Pharmacy - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer in Utah.

(21) No facility located at the same address shall be dually licensed as both a Class C pharmacy and any other classification of Class A or B pharmacy. Nothing within this section prevents a facility from obtaining licensure for a secondary address which operates separate and apart from any other facility upon obtaining proper licensure.

CA PracAct 4052.7.

Repackaging of drugs previously dispensed pursuant to prescriptions.

(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.

(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:

(1) All the information required by Section 4076.

(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.

(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.

History: Added by Stats.2001, c. 728 (S.B.724), § 27.

NABPLAW 01/2011

DC BReg 1911.

Packaging and Handling of Drugs and Medical Devices.

1911.1 The packaging and handling requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1911.2 A pharmacy shall dispense drugs or medical devices in new and clean containers or in the manufacturer's original container or package.

1911.3 A pharmacy shall dispense drugs in child-resistant containers unless there is written documentation that the patient has requested otherwise, pursuant to the Federal Poison Prevention Act of 1970, 16 C.F.R. Part 1700.

1911.4 A pharmacy shall not reuse a manufacturer's bottle or container.

1911.5 A pharmacy shall not reuse a bottle or container that has held toxic, adulterated, or misbranded substances.

1911.6 A pharmacy shall obtain drugs only from suppliers licensed or registered as required by federal and District law.

1911.7 A pharmacy shall obtain only drugs that are in the original manufacturer's or distributor's container.

1911.8 A pharmacist shall direct and supervise the compounding, **repackaging**, or prepackaging of drugs and make the final verification of the prepackaged product and document the verification.

1911.9 A pharmacy shall keep a log of drugs that have been compounded, repackaged, or prepackaged under a pharmacist's supervision. The log must contain the following information:

- (a) The name of the drug;
- (b) The name of the manufacturer or distributor;
- (c) The manufacturer or distributor's lot or control number of the drug;
- (d) The strength of the drug;
- (e) The expiration date;
- (f) The date of prepackaging or **repackaging**;
- (g) The quantity of drugs prepared; and
- (h) The name or initials of the pharmacist supervising the packaging.

1911.10 A pharmacy shall keep the log required under § 1911.09 of this chapter for five (5) years from the date of packaging. Records that are more than two (2) years old may be stored offsite as long as they can be retrieved within three (3) business days of a request.

1911.11 All drugs and medical devices held by a pharmacy shall be stored:

- (a) In a proper and safe manner;
- (b) In an appropriate container or package that provides for protection of the product;
- (c) To insure complete and accurate identification of the product; and
- (d) As required by the manufacturer, this chapter, and other applicable federal and District of Columbia laws or regulations.

History: SOURCE: Adopted at 38 DCR 6734, 6743 Nov. 8, 1991; Amended at 55 DCR 270 Jan. 11, 2008.

NABPLAW 04/2011

**IN BReg 856 IAC Rule 1-21-1.
Resale of returned substances.**

(a) This section implements and interprets IC 25-26-13-25(h) concerning the resale or redistribution of medications.

(b) For a medication to have been properly stored and securely maintained according to sound pharmacy practices, the storage and administration of medications in the institutional facility must be under the immediate control of licensed nursing personnel.

(c) If the medication was originally packaged by the dispensing pharmacy, it cannot be resold or redistributed unless:

(1) the medication has been repackaged into unit-dose packaging using packaging materials that meets Class A or Class B standards, found in the United States Pharmacopeia (U.S.P.), page 1574, published by the United States Pharmacopeia, 22nd Revision, January 1, 1990, United States Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, which standards are incorporated herein by reference; and

(2) the repackaging process complies with the standards as found in the "Proper Treatment of Products Subjected to Additional Manipulations, Section 1191" of the United States Pharmacopeia, page 1705, 22nd Revision, 1990, which section is incorporated herein by reference.

(d) A medication repackaged under the provisions of subsection (c) shall be labeled with an expiration date of not greater than one (1) year until the manufacturer's expiration date, whichever is earlier.

History: (Indiana Board of Pharmacy; Reg 21, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 128; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1334; readopted filed Sep 26, 2008, 10:55 a.m.: 20081015-IR-856080346RFA)

NABPLAW 02/2011

IN PracAct 16-42-3-5.

Exemption of drugs or devices in transit for further processing, labeling or repackaging.

A drug or device that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the drug or device was originally processed or packed, is exempt from the labeling and packaging requirements of IC 16-42-1 through IC 16-42-4 while the drug or device is in transit in intrastate commerce from one (1) establishment to the other if the transit is made in good faith for completion purposes only. However, the drug or device is otherwise subject to the applicable provisions of IC 16-42-1 through IC 16-42-4.

History: As added by P.L.2-1993, SEC.25.

NABPLAW 02/2011

KS BReg 68-7-15.

Prepackaging or repackaging of drugs.

All prepackaging or repackaging of drugs, whether in a unit dose container or multiple dose container shall conform to the following:

- (a) Packaging in advance of immediate need shall be done by a pharmacist or under his or her direct supervision.
- (b) This packaging shall be limited to drugs to be dispensed from the premises.
- (c) Proper storage conditions shall be maintained so as to preserve the stability of the drug as recommended by the manufacturer.
- (d) A proper control system shall be established for lot numbers for recall purposes.
- (e) If an area apart or separated from the prescription area is used for prepackaging or repackaging, such area must be enclosed and secured (locked) when a pharmacist is not in attendance in that area.

History: Authorized by K.S.A. 1977 Supp. 65-1630; effective May 1, 1978.

NABPLAW 03/2011

KY PracAct 217.902.

Repackaging volatile substances.

When any person removes any volatile substance from the container in which it is delivered to him and repackages it into containers not used in the ordinary course of business for the purpose of packaging such volatile substances and for the purpose of sale, a rebuttable presumption will be created that he intends to sell such substances for purposes prohibited by KRS 217.900.

History: 1980 c 138, Section 3, eff. 7-15-80.

NABPLAW 02/2011

MI PracAct 333.17766d.

Accepting, returning to stock, **repackaging**, labeling, and redispensing of prescription drugs by pharmacies operated by or under control of department of corrections.

(1) Notwithstanding section 17766(f), a pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail may accept for the purpose of resale or redispensing a prescription drug that has been dispensed and has left the control of the pharmacist if the prescription drug is being returned by a state correctional facility or a county jail that has a licensed physician's assistant, a registered professional nurse, or a licensed practical nurse, who is responsible for the security, handling, and administration of prescription drugs within that state correctional facility or county jail and if all of the following are met:

(a) The pharmacist is satisfied that the conditions under which the prescription drug has been delivered, stored, and handled before and during its return were such as to prevent damage, deterioration, or contamination that would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of the prescription drug.

(b) The pharmacist is satisfied that the prescription drug did not leave the control of the registered professional nurse or licensed practical nurse responsible for the security, handling, and administration of that prescription drug and that the prescription drug did not come into the physical possession of the individual for whom it was prescribed.

(c) The pharmacist is satisfied that the labeling and packaging of the prescription drug are accurate, have not been altered, defaced, or tampered with, and include the identity, strength, expiration date, and lot number of the prescription drug.

(d) The prescription drug was dispensed in a unit dose package or unit of issue package.

(2) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail shall not accept for return prescription drugs as provided under this section until the pharmacist in charge develops a written set of protocols for accepting, returning to stock, **repackaging**, labeling, and redispensing prescription drugs. The written protocols shall be maintained on the premises and shall be readily accessible to each pharmacist on duty. The written protocols shall include, at a minimum, each of the following:

(a) Methods to ensure that damage, deterioration, or contamination has not occurred during the delivery, handling, storage, and return of the prescription drugs which would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of those prescription drugs or otherwise render those drugs unfit for distribution.

(b) Methods for accepting, returning to stock, **repackaging**, labeling, and redispensing the prescription drugs returned under this section.

(c) A uniform system of recording and tracking prescription drugs that are returned to stock, repackaged, labeled, and redistributed under this section.

(3) If the integrity of a prescription drug and its package is maintained, a prescription drug returned under this section shall be returned to stock and redistributed as follows:

(a) A prescription drug that was originally dispensed in the manufacturer's unit dose package or unit of issue package and is returned in that same package may be returned to stock, repackaged, and redispensed as needed.

(b) A prescription drug that is repackaged into a unit dose package or a unit of issue package by the pharmacy, dispensed, and returned to that pharmacy in that unit dose package or unit of issue package may be returned to stock, but it shall not be repackaged. A unit dose package or unit of issue package prepared by the pharmacist and returned to stock shall only be redispensed in that same unit dose package or unit of issue package and shall only be redispensed once. A pharmacist shall not add unit dose package drugs to a partially used unit of issue package.

(4) This section does not apply to any of the following:

(a) A controlled substance.

(b) A prescription drug that is dispensed as part of a customized patient medication package.

(c) A prescription drug that is not dispensed as a unit dose package or a unit of issue package.

(d) A prescription drug that is not properly labeled with the identity, strength, lot number, and expiration date.

(e) A prescription drug that is dispensed in a medical institution and returned to stock for redistribution in accordance with R 338.486 of the Michigan administrative code.

(5) As used in this section:

(a) "County jail" means a facility operated by a county for the physical detention and correction of persons charged with, or convicted of, criminal offenses or ordinance violations or persons found guilty of civil or criminal contempt.

(b) "Customized patient medication package" means a package that is prepared by a pharmacist for a specific patient that contains 2 or more prescribed solid oral dosage forms.

(c) "Repackage" means a process by which the pharmacy prepares a unit dose package, unit of issue package, or customized patient medication package for immediate dispensing pursuant to a current prescription.

(d) "State correctional facility" means a facility or institution that houses a prisoner population under the jurisdiction of the department of corrections.

(e) "Unit dose package" means a package that contains a single dose drug with the name, strength, control number, and expiration date of that drug on the label.

(f) "Unit of issue package" means a package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date.

History: P.A.1978, No. 368, § 17766d, added by P.A.2004, No. 329, Imd. Eff. Sept. 23, 2004.

NABPLAW 03/2011

MN PracAct 151.415.

Long-term care resident access to pharmaceuticals act.

Subdivision 1. Title; citation. This section may be cited as the “Long-Term Care Resident Access to Pharmaceuticals Act.”

Subd. 2. Definitions. For the purposes of this section, the following terms have the meanings given them unless otherwise provided by text:

(a) “Board” means the Board of Pharmacy.

(b) “Contract pharmacy” means a pharmacy, licensed under this chapter, which is under contract to a long-term care facility.

(c) “Long-term care facility” means a nursing home licensed under sections 144A.02 to 144A.10, or a boarding care home licensed under sections 144.50 to 144.56. Facilities not certified under title XIX of the federal Social Security Act are not included in this definition.

(d) “Original dispensing pharmacy” shall mean a pharmacy, licensed in any state in the United States, which dispenses drugs in bulk prescription containers to a person who is a resident in a long-term care facility.

Subd. 3. Authorization to administer and repackage drugs. (a) A contract pharmacist or pharmacy may repackage a resident's prescription drugs, which have been lawfully dispensed from bulk prescription containers by an original dispensing pharmacy, into a unit-dose system compatible with the system used by the long-term care facility.

(b) A long-term care facility may administer drugs to residents of the facility that have been repackaged according to this subdivision. The contract pharmacy shall notify the long-term care facility whenever medications have been dispensed according to this subdivision and must certify that the repackaging and dispensing has been done in accordance with this subdivision.

(c) Drugs may be dispensed for a resident of a long-term care facility according to this subdivision, provided that:

(1) the drug is dispensed by the original dispensing pharmacy according to a current, valid prescription;

(2) the original bulk prescription container for the resident is delivered by the original dispensing pharmacy directly to the contract pharmacist or pharmacy;

(3) the contract pharmacist or pharmacy verifies the name and strength of the drug, the name of the manufacturer of the drug, the manufacturer's lot or control number, the manufacturer's expiration date for the drug, and the date the drug was dispensed by the original dispensing pharmacy;

(4) the contract pharmacist or pharmacy verifies the validity and accuracy of the current prescription order;

(5) the contract pharmacist or pharmacy repackages the drug in board-approved unit-dose packaging, with labeling that complies with Minnesota Rules, part 6800.6300, and that identifies that the drug has been repackaged according to this section;

(6) the resident for whom the medication is repackaged obtains medications from or receives medications at a discounted rate from the original dispensing pharmacy under the resident's state or federal health assistance program or a private health insurance plan; and

(7) the resident for whom the medication is to be repackaged, or the resident's authorized representative, has signed an informed consent form provided by the facility which includes an explanation of the repackaging process and which notifies the resident of the immunities from liability provided in this section.

Subd. 4. Maintenance of records. For each drug repackaged by a contract pharmacy under this section, the contract pharmacy shall maintain a record for at least two years of the following information:

(1) the name, manufacturer, manufacturer's lot number, manufacturer's expiration date, and quantity of the drug prescribed;

(2) the name and address of the resident for whom the drug was repackaged;

(3) the name and address or other identifier of the prescriber;

(4) the date the prescription was issued and the date the drug was repackaged;

(5) the date the repackaged drug was delivered to the long-term care facility;

(6) the directions for use;

(7) a copy of the label that was affixed to the repackaged drug;

(8) the initials of the packager;

(9) the initials of the supervising pharmacist; and

(10) the name and business address of the original dispensing pharmacy.

Subd. 5. Duties of the original dispensing pharmacy. Upon request of the resident, the resident's authorized representative, or a contract pharmacy or licensed health care facility acting on behalf of the resident, the original dispensing pharmacy is required to deliver medications dispensed for the resident directly to the contract pharmacist or pharmacy. The original dispensing pharmacy is further required to provide the contract pharmacist or pharmacy with the name and strength of

the drug, the name of the manufacturer of the drug, the manufacturer's lot or control number, the manufacturer's expiration date for the drug, and the date the drug was dispensed.

Subd. 6. Redispending of returned drugs prohibited. Unused drugs repackaged according to this section that are returned to any pharmacy shall not be redispensed.

Subd. 7. Immunity from civil liability. (a) A contract pharmacist or pharmacy and its employees or agents repackaging a drug acquired from an original dispensing pharmacy shall be immune from civil liability arising from harm caused by the drug due to acts or omissions of other persons outside of the contract pharmacist or pharmacy if the contract pharmacist or pharmacy properly repackages the drug according to this section.

(b) A long-term care facility and the facility's employees or agents who properly administer a drug repackaged by a contract pharmacist or pharmacy under this section shall be immune from civil liability arising from harm caused by the drug due to acts or omissions of other persons outside the long-term care facility.

Subd. 8. Handling fee. A contract pharmacist or pharmacy may charge a monthly fee of no more than 250 percent of the medical assistance program dispensing fee for each drug repackaged according to this section, but no more than \$100 per month for each individual resident.

History: Laws 2007, c. 147, art. 11, § 5, eff. July 1, 2007.

NABPLAW 02/2011

MO BReg 20 CSR 2220-2.130.

Drug Repackaging.

PURPOSE: This rule establishes requirements for drug **repackaging**.

(1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:

(A) Only products which will be directly provided to the patient may be prepackaged;

(B) Containers utilized for prepackaging shall meet, as a minimum requirement, that of Class B container standards as referenced by the United States Pharmacopoeia (USP), which has been incorporated herein by reference. Where applicable, light sensitive containers shall be used;

(C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer's expiration date or twelve (12) months, whichever is less; and

(D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer's container and is placed in a dispensing container for other than immediate dispensing to a patient.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

History: AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.130. Original rule filed Dec. 10, 1986, effective May 28, 1987. Amended: Filed Nov. 15, 1988, effective March 11, 1989. Emergency amendment filed July 1, 1991, effective July 26, 1991, expired Nov. 22, 1991. Amended: Filed July 1, 1991, effective Jan. 13, 1992. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Amended: Filed Jan. 31, 2003, effective Aug. 30, 2003. Moved to 20 CSR 2220-2.130, effective Aug. 28, 2006.

NABPLAW 03/2011

NC BReg .1416.

Repackaging.

(a) Drugs which are repackaged from within a health care facility pharmacy for subsequent dispensing or administration shall be labeled to include:

- (1) the generic or trade name, strength, and quantity of drug;
- (2) identification of the manufacturer, and lot or control number;
- (3) the expiration date of the drug being repackaged; and
- (4) cautionary notations, if applicable.

(b) A batch number assigned by the pharmacy may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy maintains a readily retrievable record which identifies, by batch number, the manufacturer, manufacturer's expiration date, and lot number of the drug.

(c) The pharmacy shall have and use facilities, personnel, operational practices, packaging material, and control procedures to assure that the purity, integrity, safety, and effectiveness of the drugs are not affected by such repackaging. All repackaging must be performed by or under the supervision of a pharmacist.

History: Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; Eff. May 1, 1997.

NABPLAW 05/2011

NV BReg NAC 639.788.

Restrictions on **repackaging pharmacy. (NRS 639.070)**

A **repackaging** pharmacy shall not:

1. Repackage more than one controlled substance or dangerous drug in each unit-of-use container.
2. Repackage a controlled substance or dangerous drug that has been previously repackaged. The pharmacy may accept delivery of such a controlled substance or dangerous drug only for the purpose of destroying it.
3. Deliver a repackaged controlled substance or dangerous drug to a person other than the patient named on the original label.

History: Added to NAC by Bd. of Pharmacy by R061-05, eff. 5-4-2006

NABPLAW 04/2011

NV BReg NAC 639.784.

Duties of repackaging pharmacy. (NRS 639.070)

Except as otherwise provided in NAC 639.788, a pharmacy may repack a controlled substance or dangerous drug that was previously dispensed by an original pharmacy if the repackaging pharmacy:

1. Makes a record of the:

(a) Name of the patient as given on the original label;

(b) Name of the controlled substance or dangerous drug;

(c) Name and address of the original pharmacy;

(d) Original prescription number;

(e) Date the controlled substance or dangerous drug is delivered to the repackaging pharmacy;

(f) Identity of the person who delivers the controlled substance or dangerous drug to the repackaging pharmacy, including, without limitation, the person's relationship to the patient;

(g) Quantity of the controlled substance or dangerous drug:

(1) Dispensed by the original pharmacy;

(2) Delivered by the patient to the repackaging pharmacy; and

(3) Delivered to the patient by the repackaging pharmacy;

(h) Date on which the repackaged controlled substance or dangerous drug is delivered to the patient; and

(i) Initials of the registered pharmacist or intern pharmacist who provides the verification required by subsection 7.

2. Does not intermingle the controlled substance or dangerous drug with the repackaging pharmacy's regular inventory or filled prescriptions.

3. Repackages the entire quantity of the controlled substance or dangerous drug delivered by the patient to the repackaging pharmacy or adds to the record required by subsection 1 an explanation of the difference between the quantity repackaged and the quantity delivered to the repackaging pharmacy.

4. Repackages the controlled substance or dangerous drug in a unit-of-use container that holds each dose in a secure and sanitary manner.
5. Completes the **repackaging** of the controlled substance or dangerous drug not later than the end of the first business day after the day the controlled substance or dangerous drug is delivered to the **repackaging** pharmacy.
6. Affixes to the container of the repackaged controlled substance or dangerous drug a label that includes:
 - (a) All information included on the original label;
 - (b) The name and address of the **repackaging** pharmacy;
 - (c) The date on which the controlled substance or dangerous drug is repackaged; and
 - (d) A disclaimer which indicates that the only activity performed by the **repackaging** pharmacy has been the **repackaging** of the controlled substance or dangerous drug. This requirement is satisfied if the label includes the words “repackaged by,” or their equivalent, followed by the name of the **repackaging** pharmacy.
7. Causes a registered pharmacist or intern pharmacist to inspect the repackaged controlled substance or dangerous drug and verify that it is:
 - (a) The controlled substance or dangerous drug named on the original label;
 - (b) Not damaged; and
 - (c) Not adulterated.

History: Added to NAC by Bd. of Pharmacy by R061-05, eff. 5-4-2006

NABPLAW 04/2011

OH BReg 4729-9-20.

Drugs repackaged or relabeled by a pharmacy.

(A) Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:

- (1) Name of drug, strength, and dosage form;
- (2) The identification of the repackager by name or by the final seven digits of their terminal distributor of dangerous drugs license number;
- (3) Pharmacy control number;
- (4) Pharmacy's expiration date or beyond-use date, which shall be within the proven period of stability of the drug. This expiration or beyond-use date shall be no later than the manufacturer's expiration date of a not previously opened manufacturer's container.

(B) A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include at least the following :

- (1) Name of drug, strength, dosage form, and quantity;
- (2) Manufacturer's or distributor's control number;
- (3) Manufacturer's or distributor's name, if a generic drug is used;
- (4) Pharmacy control number;
- (5) Manufacturer's or distributor's expiration date;
- (6) The pharmacy's expiration date or beyond-use date;
- (7) Positive identification of the pharmacist responsible for the **repackaging** of the drug.

(C) Supplemental labels created by a pharmacy that contain a barcode for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

- (1) The creation of the barcode; and
- (2) Affixing the barcode label to the drug product.

History: 2010-11 OMR pam. #4 (RRD); 2008-09 OMR pam. #6 (A), eff. 1-1-09; 2005-06 OMR pam. #6 (A), eff. 1-1-06; 2000-2001 OMR 953 (RRD); 1998-99 OMR 1621 (A), eff. 3-1-99; 1995-96 OMR 1190 (A), eff. 1-10-96; 1990-91 OMR 1099 (E), eff. 7-1-91 **NABPLAW** 05/2011

PA PracAct 960.15.

Third-party drugs in long-term care facilities.

(a) Authority.--Notwithstanding any other provision of law, all of the following may dispense a drug acquired from a drug source facility outside the long-term care facility to a patient of a long-term care facility:

(1) A pharmacist employed by a long-term care facility.

(2) A pharmacy who contracts with a long-term care facility to fill prescriptions for patients of the long-term care facility.

(b) Unit dose.--A person authorized under subsection (a) to dispense a drug shall repackage, relabel and dispense the drug in a unit dose if all of the following conditions are met:

(1) The drug is obtained from a drug source facility.

(2) There is a prescription for the drug.

(3) The prescriber has signed a form authorizing the long-term care facility to administer a drug from a drug source facility outside the long-term care facility.

(4) The patient has signed a form authorizing the long-term care facility to administer a drug from a drug source facility outside the long-term care facility and provided payment information for payment of the related fees to the pharmacy. In the case of a minor or a patient who is unable to sign the form, a parent, a guardian, an agent acting under a power of attorney or a family member is authorized to sign the form. The form must explain that a person authorized under subsection (a) to dispense a drug from a drug source facility outside the long-term care facility:

(i) is required to go through the process of **repackaging** and relabeling the drug;

(ii) may charge a fee for **repackaging** and relabeling the drug, including the amount of the fee and the frequency of its assessment; and

(iii) has immunity from civil liability arising from dispensation of the drug if the person properly repackages and relabels the drug as set forth in section 8.

(5) The nursing facility attending physician has issued an order continuing the patient's medical regime.

(6) The **repackaging** is in compliance with the Food and Drug Administration, the United States Pharmacopeia and the long-term care facility's policies and procedures.

(7) The Veterans' Administration provides the drug directly to the long-term care pharmacy in the patient's name and with the following information in preparation for the **repackaging** and relabeling:

- (i) The name and address of the dispensing pharmacy.
- (ii) The name of the dispensing pharmacist.
- (iii) The lot number of the drug.
- (iv) A copy of the original prescription.
- (v) The date the drug was dispensed.
- (vi) Directions for use, contraindications and other materials required by law to be provided to the patient.

History: 2008, Oct. 9, P.L. 1413, No. 114, § 5, effective 90 days following publication of notice required under 35 P.S. § 960.14 at 39 Pa.B. 1377 on March 14, 2009 [June 12, 2009].

NABPLAW 02/2011

SD BReg 20:51:21:01.01.

Prepackaging and repackaging.

In a pharmacy prepackaging and repackaging may only be done by a pharmacist, an intern, or a support person with direct supervision of a pharmacist. Such packaged drugs may only be dispensed or distributed from the premises where prepackaged or repackaged. Such drugs may only be distributed to a location which is under the same ownership as, or is affiliated with the premises where prepackaged or repackaged. Any container used for prepackaging or repackaging must meet United States Pharmacopeia compendium requirements. Medication packaging must meet requirements of § 20:51:13:02.01 if medications are returned for credit or redispensing.

History: Source: 29 SDR 37, effective September 26, 2002. General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 34-12B-2, 36-11-11(1).

NABPLAW 04/2011

TN BReg 1140-3-.08.

Repackaging.

- (1) Any **repackaging** of prescription drugs and devices and related materials must be supervised and controlled by a pharmacist with in-process and end-process verification and documentation.
- (2) Prescription drugs and devices and related materials which are repackaged by an institutional pharmacy practice site for subsequent dispensing and use within the institution shall be labeled to include:
 - (a) the name, strength, and quantity of prescription drug or device or related material, if larger than one (1), in the container;
 - (b) the manufacturer's name, and lot or control number;
 - (c) the expiration date of the prescription drug or device or related material being repackaged; and
 - (d) cautionary notations (e.g., refrigerate, shake well, not for injection), if applicable.
- (3) A batch number assigned by the pharmacy practice site may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy practice site maintains a readily retrievable record which identifies, by batch number, the manufacturer and lot number of the prescription drug or device or related material.
- (4) The pharmacy practice site shall have proper facilities, qualified personnel, effectual operational practices, suitable packaging material, and adequate control procedures to assure that the purity, integrity, safety, and effectiveness of the prescription drug or device or related material are not affected by such **repackaging**. All **repackaging** must be performed by a pharmacist or by a pharmacy intern or pharmacy technician under the supervision of a pharmacist.

History: T.C.A. §§63-10-404(8),(14),(26), and (28), and 63-10-504(b)(1) and (2). Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

NABPLAW 04/2011

VA BReg 18 VAC 110-20-535.

Repackaging of already dispensed prescriptions.

The primary provider pharmacy for a long-term care facility may, but shall not be required to, repackage a resident's prescription drugs repackaging by another pharmacy into the unit-dose or compliance packaging system used by the long-term care facility to assist in maintaining a uniform or more accurate system of administration.

1. Such repackaging shall only be done at the provider pharmacy.
2. Unit dose repackaging shall comply with requirements of 18 VAC 110-20-420 and compliance packaging shall comply with 18 VAC 110-20-340 B.
3. Records shall be maintained of all such repackaging of dispensed medications to include date; repackaging pharmacist's initials (or those of the checking pharmacist); and the pharmacy name, address, and prescription number of the original dispensing.
4. Any portion of a resident's medication not placed into unit dose or compliance packaging may be returned to the resident or kept for subsequent repackaging at the provider pharmacy in the original labeled container. If kept at the pharmacy, the medication shall be stored within the prescription department but separate from any working stock of drugs used for dispensing by the pharmacy, and shall only be used for the patient to whom the medication was originally

VA PracAct 54.1-3437.1.
Limited permit for repackaging drugs.

The Board may issue a limited manufacturing permit for the purpose of repackaging drugs, upon such terms and conditions approved by the Board, to the pharmacy directly operated by the Department of Behavioral Health and Developmental Services and which serves clients of the community services boards.

History: Acts 1997, c. 218. Amended by Acts 2009, c. 813; Acts 2009, c. 840.

NABPLAW 05/2011



**NABP/ASCP JOINT REPORT:
MODEL RULES FOR LONG-TERM CARE PHARMACY
PRACTICE**



AMERICAN SOCIETY OF **CONSULTANT PHARMACISTS**
1942

Executive Summary:

The National Association of Board of Pharmacy's (NABP) *Model State Pharmacy Act and Model Rules (Model Act)* serves as a resource to the state boards of pharmacy to promote uniform regulatory standards. As the number of our nation's seniors has grown, so too have the demands and challenges placed upon the pharmacists serving those seniors who live in long-term care facilities. Since the practice of pharmacy has evolved over the years with increased workload demands, changing roles of pharmacy technicians, and new technologies, so too have the regulatory guidelines and oversight responsibilities of the state boards. Not only will the practice of pharmacy need to adapt to the needs of seniors in long-term care facilities, but state boards of pharmacy and the pharmacists under their purview must understand the impact of these changes. Pharmacists practicing in long-term care must collaborate with state boards of pharmacy to update practice acts to ensure the protection of the health, safety and welfare of the public.

In late 2005, at the direction of the NABP Executive Committee, NABP convened its Task Force on Model Regulations for Long-Term Care (LTC Task Force), assisted by the American Society of Consultant Pharmacists (ASCP). The goal of the meeting was to review issues defined by and impacting the practice of pharmacy in long-term care settings and identify provisions of the *Model Act* that may necessitate revision with respect to long-term care pharmacy practice. As a result of the efforts of the Task Force, several practice areas within the long-term care setting were identified as areas in need of updating or inclusion within the *Model Act*. Most of these practice areas reflected the increasing level of service in long-term care settings and represented current standard of care that is regularly provided to patients in such settings. The suggested revisions to the *Model Act*, most of which were in the *Model Act's Model Rules for Institutional Pharmacy*, attempted to bridge the gap that currently exists between state pharmacy law and the level of service being provided in long-term care settings.

Also in late 2005, and again in mid-2006, NABP convened its Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions. This Task Force (Telepharmacy Task Force) recommended amending the *Model Act* to provide a more extensive regulatory framework for telepharmacy practice, including the use of remote dispensing systems in institutional and long-term care settings.

In sum, the revisions to the NABP *Model Act* suggested by these Task Forces represent an effort to recognize current standards of care in long-term care settings with appropriate regulation.

Subsequent to the meetings of each of these Task Forces, the recommended revisions were approved by NABP's Executive Committee. The revised *Model Act* can be found at <http://www.nabp.net/ftpfiles/NABP01/ModelActFINAL.doc>.

The goal of this Report is to provide background on the unique and highly skilled level of patient care in long-term care settings and to provide justification for updating state laws addressing pharmacy practice in these settings. As the practice of long-term care pharmacy has evolved, so too must the governing laws and regulations.

The practice issues identified by this Report are as follows:

1. The definitions of “long-term care facility” and “institutional pharmacy;”
2. The definition of prescription “drug order” to include “chart orders;”
3. The definition of “emergency medication kits” in long-term care settings and the need for starter-dose pharmacies in these settings;
4. Who may be defined as the agent of the physician in long-term care settings;
5. Repackaging medications dispensed by another pharmacy;
6. Medication therapeutic-interchange processes; and.
7. Remote pharmacy dispensing services.

1. The Definitions of “Long-Term Care Facility” (LTCF) and “Institutional Pharmacy”

Background

With the increasing demand for better quality care and a higher level of service, facilities, such as those offering assisted living accommodations or intermediate care for the mentally retarded, have come to more closely resemble traditional skilled nursing facilities. Special medication packaging and delivery services, for example, are now widely available in these facilities. These pharmacy services are needed to help ensure accurate and efficient administration of medications to residents and prevent diversion of controlled substances stored and administered in these facilities. Accordingly, these facilities should be defined in a way that recognizes this increasing level of pharmacy services. Alabama, for example, recently issued a final rule that includes assisted living in the definition of “institutional pharmacy.” Other state pharmacy practice acts should be updated to recognize the specialized care and services provided by these pharmacies.

Although the NABP *Model Act* included a definition of “long-term care facility” prior to the LTC Task Force meeting, the definition did not take into account certain long-term care facilities that receive institutional pharmacy services, but which may not be recognized as such. The LTC Task Force members agreed that the *Model Act’s Model Rules for Institutional Pharmacy* should be amended to recognize long-term care pharmacy practice as a subset of institutional pharmacy practice. With this in mind, LTC Task Force members recommended amendments to the definitions of “institutional facility” and “institutional pharmacy,” and an amendment to allow pharmacies serving long-term care facilities to provide emergency drug kits to be used in the absence of a pharmacist. Of note, these amendments exempt LTCF pharmacies from the patient counseling requirements of the *Model Act’s Model Rules for Pharmaceutical Care* and allow them to utilize a drug formulary system.

Outcomes:

- The definition of “institutional facility” in the *Model Act* was revised to include long-term care facility.
- The definition of “institutional pharmacy” was modified to mean “any place which is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act that provides Pharmaceutical Care to an Institutional Facility and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as “Drugs”) are Dispensed, Compounded, and Distributed.”

2. Definition of Prescription Drug Order to Include Chart Orders

Background:

In the current long-term care practice setting, caregivers commonly refer to the patient's medical chart to determine when a prescription drug refill is needed and to record, monitor, and make necessary changes to a patient's medication therapy. The caregiver or health professional administering the medication uses the "chart order" within the medical chart as the reference for completing the medication administration record. This one consistent record is essential to the delivery of quality health care and to ensure that medication administration errors are minimized. With this in mind, LTC Task Force members felt the *Model Act* should be updated to incorporate this unique, yet important aspect of patient care in long-term care settings. Prior to the LTC Task Force meeting, the *Model Act* included a definition of "Prescription Drug Order," which includes the date of issuance, name, strength, and dosage form of the drug prescribed, directions for use, and the prescriber's signature. The LTC Task Force, however, recognized that other components of a "Prescription Drug Order," such as the full name and street address of the patient, the DEA number of the prescribing practitioner, quantity of the drug prescribed, and number of refills, are not typically included on orders in institutional settings. The LTC Task Force, therefore, recommended the recognition of orders in institutional settings via the inclusion of the term and definition for "Chart Order" as a lawful and valid prescription drug order utilized in an institutional facility.

Outcome:

A definition of Chart Order was created in the *Model Act* under the *Model Rules for Institutional Pharmacy*.

3. The Need for Starter Dose Pharmacies in the Long-Term Care Setting and Definition of Emergency Medication Kits for Use Therein

Background:

Arbitrary restrictions on the availability of initial doses of medications in long-term care facilities compromise the quality of care rendered to residents. There are situations where long-term care residents require immediate care that may easily be provided by an emergency drug kit or a starter dose pharmacy. These patients, especially those who are frail elderly, cannot wait until the next day to receive their medications. Emergency kits and starter dose pharmacies allow the patient to receive an immediate dose of a medication not currently on that patient's medical chart. Use of starter dose pharmacies is particularly important in rural areas where the closest pharmacy may be 50 miles away.

The LTC Task Force agreed that institutional pharmacies, and specifically those that provide services to long-term care facilities, should be allowed to utilize centralized prescription processing arrangements to provide continuous services to inpatients. "Centralized Prescription Processing" and "Centralized Prescription Filling" as recognized in the *Model Act*, allow a pharmacy to process 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. The LTC Task Force members recommended that centralized prescription services be incorporated into the *Model Rules for Institutional Pharmacy*, recognizing the use of a valid chart order and specifying that the institutional pharmacy outsourcing services have been approved by the institutional facility.

Outcomes:

- The need for emergency medications in long-term care settings was resolved by amending the *Model Rules for Institutional Pharmacy* to allow the use of emergency kits to meet the immediate therapeutic needs of patients pursuant to a Chart Order.
- The need for starter-dose pharmacies in the long-term care setting was addressed by creating a new section in the *Model Rules for Institutional Pharmacy* entitled “Centralized Prescription Processing for Immediate Need,” which allows an institutional pharmacy to outsource services to another pharmacy under specific guidelines defined in the *Model Act* for the purposes of assuring that drugs or devices are attainable to meet the immediate needs of patients of the institutional facility.

4. Who Can Be Defined as the Agent of the Physician in Long-Term Care Settings

Background:

At this time, the US Drug Enforcement Administration (DEA) does not recognize long-term care or nursing facility staff as agents of prescribers, prohibiting them from transmitting orders for controlled substances for prescribers to pharmacies. This position was conveyed in an April 2001 *Federal Register* notice, as part of DEA’s efforts to solicit comments on preventing accumulation of controlled substances at long-term care facilities. In that notice, the DEA stated that since no legal agency relationship exists between the long-term care facility nurse and the physician, long-term care facility nurses who relay changes in medication therapy to pharmacists are not in compliance with legal controlled substance prescription requirements.

In the long-term care setting, physicians are not on-site at the nursing facility and typically visit the facility only once per month to see patients. As a result, they rely on nursing facility staff to transcribe and communicate orders to the long-term care pharmacy. These orders are a part of the residents’ medical chart and are recognized as valid prescriptions in many states. In fact, NABP recently adopted a resolution formally recognizing chart orders as valid prescription orders in the long-term care setting.

Because many of the residents in long-term care face chronic or acute pain situations, allowing the nurse to act as an agent of the physician will result in better patient care, especially in the area of pain management. In many of these cases, the orders are simply refills for controlled substance medications that have run out. Currently, refill requests must be faxed to the physician’s office and then faxed to the long-term care pharmacy each time the patient’s medication runs out and a refill is needed, regardless of the day or time, and regardless of whether or not the off-site physician is near a fax machine. This process would be much more efficient if the nurse were able to take a verbal order from the physician and then communicate that order along to the long-term care pharmacy. This, however, is not allowed by DEA. To

remedy this, DEA has suggested that nurses, rather than contact the physician for an order, contact the provider pharmacy, and have the pharmacist contact the physician. This, according to the DEA, will avoid multiple contacts or phone calls to the physician. This may not, however, be the case. If the prescribing physician has a question about the patient that only the nurse can answer, multiple contacts and phone calls are still necessary. Again, more effective patient care would be provided if nurses could be considered agents of the prescribing physician in these instances.

Prior to the LTC Task Force meeting, the *Model Act* did not specify the legality of the relationship between a practitioner and a practitioner's agent. The *Model Act*, therefore, was amended to clarify that an agency relationship between a facility nurse and prescriber can exist in conformance with facility policies and procedures.

Outcome:

- In the NABP *Model Act*, it was clarified that an agency relationship between a prescriber and a staff nurse can exist, in compliance with state law, at an institutional facility, but that such agent must be authorized by that facility to do so in the facility's written policies and procedures in accordance with applicable state and federal laws. In addition to this, the LTC Task Force urged NABP to adopt a resolution to encourage the DEA to reexamine its interpretation of the agency relationship between the long-term care facility and alternate care site nurses to consider recognizing the agency relationship in the presence of written facility policies and procedures. This would allow the long-term care nurse to legally communicate controlled substance orders and changes to such orders to pharmacists responsible for the care of the patient. This resolution was subsequently approved by NABP's member boards.

5. Repackaging Medications Dispensed by Another Pharmacy

Background:

In formulating this recommendation, the LTC Task Force members emphasized the difference between "repackaging" and "prepackaging." According to the *Model Act*, the act of "repackaging" is considered "manufacturing," which is defined as the "production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis." Manufacturing includes the packaging or repackaging of a drug or device or the labeling or relabeling of the container of a drug or device for resale by pharmacies, practitioners, or other persons."

LTC Task Force members wanted to distinguish pharmacies that perform repackaging and re-labeling operations beyond the usual conduct of dispensing from those performing "prepackaging" operations, emphasizing that the former are subject to state and federal laws and regulations with respect to manufacturing. The state boards of pharmacy and the FDA recognize that many pharmacies engage in "prepackaging." According to FDA's Compliance Policy Guide 7132.06, FDA recognizes prepackaging by hospital pharmacies dispensing to patients of the hospital. In the long-term care pharmacy setting, this practice is similar with respect to long-term

care pharmacies prepackaging medications for residents of the long-term care facility served by that pharmacy. As stated in FDA Compliance Policy Guide 7132.06:

“Prepackaging

We do not believe that “prepackaging” by the hospital pharmacy for dispensing within the hospital, or for outpatient dispensing, or for transferal to another unit of the hospital, would require registration under Section 510 of the Federal Food, Drug, and Cosmetic Act. However, repackaging of a drug which is sold to another hospital, whether or not such other hospital is under the control of the same corporation, would require registration under Section 510.”

It is standard practice in today’s long-term care environment for pharmacists to prepackage medications from the manufacturer’s original packaging into unit dose blister cards for residents of long-term care facilities. The practice of providing specialized or compliance packaging has been a hallmark of long-term care pharmacy practice to help reduce medication administration errors and assist facility and pharmacy staff in identifying drug diversion. This practice was recently recognized by the Centers for Medicare & Medicaid Services (CMS) as one of ten service and performance criteria that is commonly provided by long-term care pharmacy.

Accordingly, the boards of pharmacy in many states, including Arizona, Minnesota, Montana, and Nevada, have developed prepackaging regulations that specify labeling and recordkeeping requirements. The LTC Task Force members, recognizing that prepackaging activities are a common occurrence, suggested that the *Model Act* incorporate specific regulatory guidance for this activity.

Outcome:

- By creating a definition under the *Model Rules for Pharmaceutical Care* for “prepackaging,” NABP distinguished “prepackaging” from “repackaging,” and clarified that repackaging medications previously dispensed by another pharmacy is considered manufacturing.

6. Medication Therapy Management Services

Background:

NABP’s *Model Act* allows pharmacists to provide medication therapy management services as an element of pharmacist care.¹ Under the Model Act, medication therapy management services are intended to optimize therapeutic outcomes for patients and may include:

- (1) Performing or obtaining necessary assessments of the patient’s health status;
- (2) Formulating a medication treatment plan;

¹ NABP’s Model Act definition of “medication therapy management” is derived from the definition approved July 27, 2004 by the Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the American Pharmacists Association, the American Society of Health-System Pharmacists, the National Association of Boards of Pharmacy**, the National Association of Chain Drug Stores, the National Community Pharmacists Association and the National Council of State Pharmacy Association Executives.

** Organization policy does not allow NABP to take a position on payment issues.

- (3) Selecting, initiating, modifying, or administering medication therapy;
- (4) Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- (5) Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- (6) Documenting the care delivered and communicating essential information to the patient's other primary care providers;
- (7) Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications;
- (8) Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens;
- (9) Coordinating and integrating Medication Therapy Management services within the broader health care-management services being provided to the patient; and
- (10) Such other patient care services as may be allowed by law.

The NABP Model Act recognizes that certain Medication Therapy Management Services may need to be performed within the confines of a collaborative practice agreement or formulary system managed by a Pharmacy and Therapeutics Committee within an institutional setting. These services can prove invaluable to patient care. In long-term care settings, collaborative agreements or formulary systems that allow pharmacists to select, initiate, and/or modify medication therapy can be particularly beneficial.

It is important to differentiate medication therapy management services from medication regimen review services in the long-term care setting, which are mandated as a component of a broad range of nursing facility regulations in the Centers for Medicare and Medicaid Services (CMS) State Operations Manual (SOM).

Outcome:

- NABP encourages state boards of pharmacy to review and seek revision of statutes or rules to strengthen legislation for pharmacist involvement in medication therapy management services, including those that allow pharmacists to select, initiate and/or modify medication therapy services pursuant to a collaborative practice agreement with a prescriber.

7. Remote Pharmacy Dispensing Services

Background:

NABP's Telepharmacy Task Force developed a framework for the provision of remote pharmacy services while considering current regulatory and patient safety standards, allowable scope of practice, the use of pharmacy support personnel, and maintenance of quality assurance procedures. The Telepharmacy Task Force developed these recommendations recognizing the national pharmacist shortage and the potential to effectively provide pharmacist care services using electronic technologies to patients at a distance.

Outcome:

- NABP added to the *Model Act* definitions of "remote pharmacy," "remote dispensing site," and "coordinating pharmacy" to provide the basic framework for the provision of remote

pharmacy services. A “remote pharmacy” is a “pharmacy staffed by a pharmacist, pharmacy intern, or certified pharmacy technician that is electronically linked to the coordinating pharmacy via a computer system and/or a video/auditory communication system approved by the board.” A “remote dispensing site” is a site located within an institutional facility or a clinic that utilizes an automated pharmacy system and that is electronically linked to the coordinating pharmacy via a computer system and/or a video/auditory communication system approved by the Board. A “coordinating pharmacy” is a pharmacy responsible for the practice of telepharmacy performed at Remote Pharmacies and Remote Dispensing Sites.”

- The *Model Act* was amended to add regulations addressing the registration/licensure of the primary and remote sites (coordinating pharmacy, remote pharmacy, and remote dispensing site), remote site personnel, remote patient counseling, the use of automated dispensing technologies, security, policies and procedure maintenance, quality assurance, recordkeeping, and the restriction of remote sites to areas or communities that are underserved.

Conclusion:

The NABP and ASCP recommend that the seven practice issues addressed in this Report be reviewed and adopted as appropriate by state boards of pharmacy. Pharmacists must understand the impact of these changes and collaborate with state boards of pharmacy to update state pharmacy practice acts to ensure the protection of the health, safety and welfare of the public. This will allow pharmacists to practice to the full extent of their skills and knowledge and serve the unique needs of the growing population of frail elderly patients residing in long-term care facilities.

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